Exhibit P-1

MedWatch Report

B.5.

Introduction

I am a Board Certified Anesthesiologist with special training and interest in cardiac and pediatric anesthesiology. I spent many years on the academic faculty at the University of Minnesota and have recently moved to private practice. As a practicing anesthesiologist—as well as a clinical researcher—I have observed numerous problems with forced-air warming systems ("FAW") that I believe put patients at risk. Specifically, I have studied Bair Hugger® FAW systems manufactured by Arizant, Inc. The results of much of this research have been disclosed to the executives at Arizant. Despite the fact that they have been aware of these problems for over two years, I have not seen any efforts on their part to correct the problems or to report the problems to either the authorities or to their customers.

Since I helped Arizant (Augustine Medical at that time) develop the intraoperative Bair Hugger product when it was introduced into the operating room about 20 years ago, I feel somewhat responsible for these newly discovered patient risks. I also find Arizant's behavior regarding the safety problems with their products - the fact that they appear to be in total denial regarding these problems-- to be very disturbing. That is why I am compelled to make this complaint to the FDA. This report summarizes my research and that of others as well as information that I have gathered from public sources and from industry.

I will address the following five risks to patient safety:

1. Bacterial contamination of FAW blowers—Multiple published studies, including my own, establish that the internal airflow paths of Bair Hugger blowers are routinely contaminated with multiple strains of pathogenic bacteria and that millions of particles per hour are commonly blown from the Bair Hugger systems into the sterile field.

2. Degradation of filtration—Despite representations by Arizant to the FDA and European regulators that the intake filters on its Bair Hugger blowers are HEPA (99.97% efficient), the efficiency of the filters has recently been reduced to 61.3%. As a consequence, the uncleanable interior of Bair Hugger blowers becomes more easily contaminated—and the contamination is blown into the surgical field.

3. Destruction of laminar flow protection by waste FAW heat—Contaminated hot air escapes from Bair Hugger blankets near the (non-sterile) operating room floor, mixes

with "dirty" air, then rises into the laminar flow currents that are intended to protect patients in ultra-clean surgeries. Not only is the laminar flow protection defeated, but the contaminated air also falls into the sterile field as it cools.

4. Breach of reprocessing standards—Arizant has refurbished thousands of Bair Hugger blowers. As noted above, these blowers are contaminated with pathogens. Arizant, however, does not sterilize—or even clean—the interiors of these blowers before placing them back into service. This creates the risk that pathogens may be transported from one clinical facility to another.

5. Failure to meet FDA reporting obligations—Upon becoming aware of the contamination of its systems, the consequences of the reduction of filter efficiency and the destruction of laminar flow protect caused by its systems, Arizant was required to report these issues to the FDA. It has not done so.

Background

A. Benefits of surgical normothermia

Because of the published research of D. Sessler, A. Kurz and others during the last twenty years, the benefits of maintaining surgical normothermia are undisputed. Normothermic patients spend fewer days in the ICU, require less blood, incur fewer morbid cardiac events, and –most importantly—suffer significantly fewer surgical infections than patients who become hypothermic during surgery. [i]

The benefits of normothermia have been acknowledged globally, and active patient warming has become a standard of care in many countries. In the United States, guidelines issued through the Surgical Care Improvement Project ("SCIP") strongly encourage "active warming" in any procedure lasting longer than one hour. [ii] In the United Kingdom, guidelines promulgated by the National Institute of Clinical Excellence ("NICE") forbid beginning surgery unless the patient's temperature is at least 36°C. The patient may not be released to the ward until 36°C has been restored. [iii]

B. Dominance of Bair Hugger therapy

Disposable forced-air warming blankets—and Bair Hugger therapy in particular—dominate the field. SCIP only recently added electrically conductive warming to its definition of "active warming," finally offering a practical alternative to FAW. According to IMS, however, Bair Hugger therapy commands a US market share of approximately 95%. Virtually all of the Bair Hugger blowers in use in the United States are owned by Arizant and "loaned" to hospitals in return for the purchase of disposable warming covers.

C. Early identification/discounting of risks

Concerns that blowing hot air around the operating theatre could risk patient safety were expressed early in the life of the technology. These concerns were summarily rejected and most clinicians now wrongly believe that the technology is safe. The rejection of the risk first occurred in an invited review of the technology by Sessler published in *Anesthesiology* in 2001. Sessler wrote:

> Surgeons are sometimes concerned that increasing air flow in operating rooms will increase contamination within surgical incisions. All forced-air warming include filters that essentially eliminate bacteria in the heated air. Furthermore, studies have demonstrated that the number of colony-forming units recovered from operating rooms is not increased by forced-air blowers. Finally, use of forced-air heating has been shown to reduce the incidence of surgical wound infection threefold by improving host defense. There is therefore no empirical support for the theory that forced-air heating increases infection risk. [iv] (Emphasis added.)

Unfortunately, the key unsupported assertion made by Sessler —*"All forced-air warming include filters that essentially eliminate bacteria in the heated air."*— was untrue regarding Bair Hugger when the assertion was made. Since then, Bair Hugger filtration has gotten significantly worse. (See Sec. II, below) Additionally Sessler, like everyone else, was focused on the wrong issue – waste air, when the real issue is waste heat. Therefore, any of his opinions regarding the risks of FAW must be suspect

I. Bacterial Contamination of FAW blowers

A. Early research

In the late 1990s and early 2000s, several researchers raised issues regarding the safety of Bair Hugger blowers and demanded design changes. In 1997 M.S. Avidan cultured pathogen organisms from the air blown from 40% of forced-air blowers, stating as follows:

> We conclude that these warming devices are a potential source of nosocomial infection… (and suggesting that a) … microbial filter fitted to the nozzle of the hose could be incorporated into the design of the warmer to reduce the risk of contamination.[v]

In 2002 N. Baker and D, King wrote in a letter to the *Journal of Hospital Infection* that swabs from the exterior and interior of the blower all resulted in "heavy growth of bacteria." Air blowing from the end of the hose grew colonies of coagulase-negative *staphylococci, Bacillus spp., and Micrococcus spp.* "At present," they wrote, "there seems insufficient evidence to justify the routine use of forced air warming units as a intraoperative measure during ultra clean orthopaedic surgery." [vi]

In 2003, M. Scherrer of the Institute for Environmental Medicine and Hospital Epidemiology, University Hospital of Freiburg, noted that "The air emitted from these (FAW) blankets also disturbs the ultra clean field and preliminary investigations have shown an increase of bacteria in the operating field when the warming system is on." [vii]

In 2004, after unsuccessfully fighting outbreaks of *Acinetobacter baumannii* at Leiden University Medical Centre, infection control personnel isolated the bacteria to the filters of Bair Hugger blowers. After the pathogenic dust was removed, the outbreak ended, causing researchers to state:

> After…changing the filters of the Bear (sic) Hugger apparatus, the outbreak came to an end, suggesting that this apparatus was indeed the source of the outbreak. [viii]

Dr. Suzanne Beavers, Epidemic Intelligence Service Officer of the Kentucky Department of Public Health, apparently reached a similar conclusion. In three separate publications (two speeches and a newsletter), Dr. Beavers identified Bair Huggers as a source of infectious outbreaks, repeatedly referring to them as "reservoirs of infection." (Annex A)

B. Recent research

1. In 2009, microbiologists from Stanford University essentially replicated the study done by Baker and King in 2002. They found that the internal air-flow paths of 12 of 29 Bair Hugger blowers cultured positive for pathogens and noted the recommendation that "an additional microbial filter be fitted to the distal end of the BH hose." (Annex B)

2. A 2010 study published in *Orthopedic Reviews* was authored by a team including myself and D. Leaper, the UK surgeon who chaired NICE's Surgical Site Infection Guidance Development Group. Prof. Leaper's team sampled 25 Bair Hugger blowers in their operating room environment. The results:

* Pathogenic bacteria were cultured from the internal air-flow paths of 94% of the blowers.

* 32% of the blowers tested were emitting internally generated airborne contamination in the size range of bacteria.
* 24% of the blowers tested were emitting "significant levels of internally generated airborne contamination."

The contamination, the authors stated, originated inside the blowers. The authors recommended adding a distal hose filter.[ix]

3. Another study by Prof. Leaper's team has been accepted for publication in the *American Journal of Infection Control.* (Annex C) In that study, 52 Bair Hugger blowers were sampled in operating rooms. In summary:

* Micro-organisms were cultured from the internal air-flow paths of 92.3% of the blowers including *Staphylococcus aureus* (13.5%), coagulase negative *Staphylococcus aureus* (3.9%) and methcillin resistant *Staphylococcus aureus* (MRSA) (1.9%).
* 58% of the Bair Hugger blowers tested were found to be internally generating and emitting significant levels of airborne contaminants >0.3 μm in size (germ size), up to 35,272 particles per ft^3 of air (80 million particles per hour).

4. In a recent study (in submission for publication) by Dr. Michael Reed, an orthopedic surgeon in the United Kingdom, 23 Bair Hugger blowers were sampled in operating rooms. The findings:

* Micro-organisms were cultured from the internal air-flow paths of 100% of the blowers including coagulase negative *Staphylococcus aureus* (74%), mold (26%) and *Micrococci* (9%).
* 100% of the blowers were emitting internally generated particles >0.3 μm in size, up to 112,000 particles per ft^3 of air (300 million particles per hour).
* In the most contaminated blower, emitted particle count was 40 times greater than intake particle count.

5. In an abstract submitted to the American Academy of Orthopedic Surgeons 2011 annual meeting by Dr. M Reed, 75 Bair Hugger blowers in active use in 11 hospitals were cultured. Blowers with 93.8% efficient inlet filters were compared to blowers with 63.8% efficient inlet filters. The findings:

* Micro-organisms were cultured from the internal air-flow paths of 100% of the blowers with 63.8% efficient filters.
* Micro-organisms were cultured from the internal air-flow paths of 92% of the blowers with 93.8% efficient filters.

* There was a significant increase in common SSI pathogens (*s. aureus and s. epidermidis*) in the blowers with the lower 63.8% efficient filters (74% v 17%; $p<0.01$). (Annex D)

C. Consequences of contamination

Of course, it is not unusual for medical devices used during surgery to become contaminated. For that reason, the FDA and international regulators have developed strict rules regarding labeling, instructions for use and cleaning protocols that manufacturers must provide.

1. Violation of FDA regulations

Under FDA labeling regulations, 21 CFR 801, a device must have adequate directions, which include instructions on preparing a device for use. Instructions on how to reprocess (i.e., clean, and disinfect or sterilize) a reusable device are important steps in preparing a device for the next patient. Similarly, IEC 60601-1 deems labeling and instructions for use "a critical component of a medical device." An operator's manual is required to provide information on cleaning, preventive inspection, and maintenance to be performed by the user. In addition, the frequency of such maintenance must be specified. Manuals must provide complete instructions to ensure that routine maintenance can be performed safely.

The information provided by Arizant, however, does not even acknowledge the possibility that the internal air-flow path could be contaminated, much less provide instructions as to how the contamination can be abated. Cleaning instructions suggest merely that cleaning staff wipe the exterior of the blower with a damp cloth. [x]

2. Violation of United Kingdom regulations

(a) Health Act of 2006

As recently acknowledged by NICE, Bair Hugger is a two-part device: the paper/plastic blanket is disposable; the blower is reusable.[xi] Reusable devices used in operating theaters are subject to special legal requirements in the UK. The Health Act of 2006 is unambiguous regarding such reusable devices:

Appendix 2, f. -- Decontamination of reusable medical devices

"Effective decontamination of reusable medical devices is essential."
"Reusable medical devices and other devices should be decontaminated in accordance with manufacturer's instructions and current guidelines."

Arizant's Bair Hugger system violates both requirements of the Health Act. The reusable portion of the system—the blower—cannot be effectively decontaminated between surgeries because the contamination is sealed inside the blower. As soon as the blower is activated, the contamination aerosolizes, exiting the blower and spreading into the sterile field.

(b) Medicines and Healthcare Products Regulatory Agency ("MHRA")

The manual of the Microbiology Advisory Committee, a group of experts reporting to the MHRA on disinfection and sterilization practices, confirms the requirement for the decontamination of reusable devices:

> Manufacturers of reusable medical devices are required by the Medical Devices Directive to supply clear written decontamination instructions, which should include appropriate cleaning, disinfection or sterilization methods. [xii]

As noted, Arizant offers no instructions for decontamination whatsoever. The Bair Hugger Operating Manual suggests only that the outside of the blower box be wiped with a damp cloth. Having worked at more than a dozen hospitals, I have never seen any attempt to clean the internal airflow path or been informed of any such procedure.

3. Violation of EU Medical Devices Directive (MDD")

Medical devices in the UK and throughout the EU are governed by the MDD. Annex 1 of the MDD sets forth the Essential Requirements that each device must meet before achieving *Conformité Européenne* ("CE") and receiving the CE Mark. Essential Requirements include:

- The devices must be designed and manufactured in such a way that, when used under the conditions and purposes intended, they will not compromise the health or safety of patients, users or other personnel.
- Safety principles must be utilized for the design and construction, and they should include state-of-the-art technologies.
- The devices must meet all claimed performance criteria.
- The devices must continue to function as intended, without compromising safety or health, when subjected to normal conditions of use.

The Bair Hugger system fails to meet each of these Essential Requirements. When used as intended—in the operating theatre—the system compromises the safety

of patients by spewing bacteria into the patients' open surgical wounds. By failing to include a hose-end filter to capture aerosolized bacteria, as researchers have demanded since 1997, Arizant has ignored safety principles and avoided even basic technological protections. Under normal conditions of use, the blowers incubate pathogenic bacteria and blow the bacteria into the sterile field, clearly compromising the safety of patients.

Clause 13.6(h) of Annex I addresses issues identical to those addressed by the FDA in 21 CFR 801:

> If the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of sterilization of the device to be resterilized, and any restriction on the number of reuses.

As noted above, instructions to wipe the outside of the blower with a damp cloth does not even purport to address the issue of internal contamination.

Section 8.1 of the MDD also addresses the issue:

> **8.1 Infection and Microbial Contamination**
>
> The devices and their manufacturing processes must be designed in such a way as to eliminate or reduce as far as possible the risk of infection to the patient, user and third parties, the design must allow easy handling and, where necessary, minimize contamination of the device by the patient or vice versa during use.

A system that incubates pathogens, blows those pathogens into the surgical site, and is impossible to clean is hardly "designed in such a way as to eliminate or reduce…the risk of infection…."

D. Culpability of Arizant

While Arizant may have been aware of the contamination risk created by Bair Hugger blowers even prior to October 2007, the facts were explicitly laid before Arizant executives at the annual meeting of the American Society of Anesthesiologists in San Francisco October 13-17, 2007. In a brochure and video presentation entitled "Blowing Air Is Risky," (Annex E) Arizant competitor Hot Dog International LLC publicly presented the following facts:

- A department of public health in the U.S. called Bair Hugger blowers "reservoirs of infection."
- Particle counters measured more than 50 million bacteria-sized particles per hours spewing from Bair Hugger blowers.
- An outbreak of multi-drug resistant *Acinetobacter* had been traced to the inside of Bair Hugger blowers, as reported in *Infection Control and Hospital Epidemiology*.
- Germ colonies could be cultured by swabbing inside Bair Hugger units and by impacting the air blown from the hose on a culture plate.

Copies of the brochure were provided to employees of Arizant during the meeting. (Affidavit of Dr. Scott Augustine, Annex F.)

In response to the Blowing Air Is Risky brochure, Arizant filed suit against Hot Dog International in Germany. In papers filed with the German court, Arizant repeatedly attacked the validity of the peer-reviewed, published research and asserted that any problem with contamination could be traced to the failure of Arizant's customers to change filters as required. (German documents are available upon request.) For example, Arizant alleged:

- Bair Hugger blowers were only a "possible" source of the *Acinetobacter* outbreak at Leiden University Medical Centre. (In fact, the authors stated that the data suggested that Bair Hugger blowers were "indeed the source of the outbreak.")
- The *Acinetobacter* outbreak could not be blamed on Bair Hugger because the filters were not changed on schedule. (In fact, dirty filters should further restrict airflow, reducing—rather than increasing—airborne contamination.)
- The study conducted by microbiologists at Stanford University was not scientifically valid. (The study selected for publication by the American Society of Anesthesiologists.)
- Arizant inexplicably defended itself against Dr. Beavers' "reservoirs of infection" statements by explaining that the article and speeches identified Bair Hugger blowers as only one of several "reservoirs of infection," not the only one.

After Hot Dog International provided proof to the German court regarding the accuracy of each statement, Arizant recast its claim as an objection to the manner in which Hot Dog International made its statements, not the underlying accuracy of the statements themselves.

More recently, a law firm representing Arizant threatened a British medical devices distributor with litigation if the distributor did not stop informing customers of the research relating to FAW. (Dechert letter at Annex G)

Rather than encourage scientific research concerning contaminated Bair Hugger blowers, Arizant seems to be attempting to thwart such research. Recently an employee of Arizant threatened Prof. Leaper with "repercussions" if revelations of the risks of FAW did not cease. (Statement of Steve Hammant-Stacy, Annex H) In May, Arizant's vice-president of sales, Robert Buehler, contacted Prof. Leaper in England, offering financial assistance if Leaper would conduct research on behalf of Arizant. (Statement of Robin Humble, Annex I.) Shortly thereafter, Prof. Leaper notified his research team that he would not do any more research on FAW contamination or laminar flow disruption. (Affidavit of Dr. Scott Augustine, Annex F)

In 2009, on the eve of research to be conducted by doctors that would have tested the Bair Hugger blowers located at University Hospital in Caen, France for contamination, Arizant quickly removed every Bair Hugger blower in the facility and replaced them with 80 new blowers. At an approximate retail price of $1,400, this cover-up cost Arizant more than $112,000. (Id.) Similarly, just before UK orthopedic surgeon Dr. Mike Reed was to begin testing the contamination levels of Bair Hugger blowers at a National Health Service Hospital in Northumbria, Arizant replaced all the hospital's blowers with new (and, obviously, uncontaminated) units. Id.

E. Recommendations

Although MedWatch does not specifically provide for Reporters to make recommendations concerning safety improvements, I will nevertheless make suggestions throughout this report. As regards the bacterial contamination, I recommend:

1. As demanded by several clinical researchers, Arizant and other manufacturers should be required to place a HEPA filter on the hose-ends of FAW blowers. As described below, this action would also bring FAW blowers into conformity with operating room ventilation standards promulgated by the Hospital Infection Control Practices Advisory Committee of the National Center for Infectious Diseases ("HICPA").

In its 1999 "Guideline for Prevention of Surgical Site Infections," HICPA urged that inside operating theatres, hospitals should "filter all air, re-circulated and fresh, through the appropriate filters per the American Institute of Architects' recommendations."[xiii] That 1996 guideline was updated by the 2005 Standard 170, *Ventilation of Healthcare Facilities* produced by the American Society of Heating, Refrigerating and Air-Conditioning Engineers ("ASHRAE").

Standard 170 covers all equipment used for heating air in healthcare facilities. For inpatient surgery facilities, double filtration is required, as has been recommended by several Bair Hugger researchers. Filter bank No. 1 (inlet filtration) must achieve MERV

8 (40-50% efficiency) and filter bank No. 2 (outlet filtration) must achieve MERV 14 (90% efficiency). Moreover, at Sec. 5.7.2, the ASHRAE standard states:

> All air distribution devices shall meet the following requirements:
>
> a) Surfaces of air distribution devices shall be suitable for cleaning.
>
> b) The supply diffusers in Class B & C surgeries shall be designed and installed to allow for internal cleaning.

2. FAW air-circulation systems should be required to meet all aspects of ASHRAE Standard 170, including those listed above. Since "internal cleaning" is impossible, however, both inlet and outlet filters should be HEPA. Otherwise, pathogens will continue to breed inside the blowers and be blown into the sterile field.

3. Contaminated blowers should be recalled from the field and decontaminated before being put back into service.

4. Warning labels should be required, identifying the risk of internal contamination.

II. Degradation of filtration

Two models of Bair Hugger blowers can be found in the field. In the United States and around the world, tens of thousands of the Model 505, introduced in the early 2000s, remain in use. The Model 750 blower became available a few years ago, and all new Bair Hugger blowers sold since by Arizant have been Model 750s.

A. Misrepresentations to the FDA

In an effort to obtain 510(k) clearance for its Model 750 blower, Arizant successfully established substantial equivalence between the Model 750 and its predecessor, the Model 505. In a communication received by the FDA on September 6, 2000 identified as K001149, Arizant represented to the FDA that the filtration of the Model 750 was "HEPA," an improvement over the " .2 micron filter" of the Model 505. (Annex J) The US Centers for Disease Control defines a HEPA (High Efficiency Particulate Air) filter as an air filter that removes more than 99.97% of particles 0.3 microns or larger.[xiv]

Until recently, the filtration efficiency of the Model 505 was 93.8%. As certified by an independent laboratory, however, replacement filters for the Model 505 have recently been reduced to 63.8 % efficiency. Similar testing revealed that the filter in the Model 750 blower achieves only 61.3% efficiency. (Annex K) The previously mentioned two studies conducted by Prof. Leaper's group (one of which has been

accepted for publication by the *American Journal of Infection Control*) revealed average filtration efficiencies to be 61.3% and 63.8% respectively.

This degradation of filtration efficiency by Arizant apparently occurred after Arizant's executives were informed of the contamination of their blowers at the October 2007 annual meeting of the American Society of Anesthesiologists. Arizant, however, had long known that inadequate filtration can lead to contamination of the surgical field. In a letter to the FDA regarding its cardiac FAW blanket received on June 26, 1997 identified as K964673, Arizant admitted that "air blown intraoperatively across the surgical wound may result in airborne contamination." (Annex L) Arizant successfully argued, however, that wound infections would be avoided because "[all] Bair Hugger Blankets designed for use in the operating room feature a tape barrier which prevent (sic) air from migrating toward the surgical site." Id.

While the statement regarding the universality of a tape barrier may have been true when made, it is true no longer. At least seven models of Bair Hugger blanket (generally called the "Underbody Series") do not even attempt to contain contaminated air within the taped edge of the blanket. Instead, they blow contaminated air directly toward the surgical field. [xv] Also, my personal experience shows that the tape barrier frequently becomes dislodged during preparation for surgery.

Even Arizant's 1997 representation that the tape barrier could contain the contaminated air was erroneous. In fact, the hot air escapes near the floor, mixes with dirty air and rises (even against laminar flow) into the sterile field. (See video attached as Annex M and Section III, below.)

B. Other misrepresentations by Arizant

According to the Inadvertent Perioperative Hypothermia Costing Report prepared by the NHS's Purchasing and Supply Agency ("PASA") in the UK, a distinguishing feature among FAW devices is the "…presence of an air filter capable of removing very small (0.2-0.3 micron) airborn particles from the air drawn into the device, as an infection control measure."[xvi]

Based on this false belief, both NICE and MHRA have concluded that Bair Hugger blowers do not present a risk of infection. The false belief arises from representations by Arizant in its published Product Specifications that Bair Hugger filtration is "high efficiency" (HEPA) (Annex N) as well as direct representations to MHRA and PASA. As explained above, these representations are false. Moreover, former engineering and product development employees of Arizant have stated in an affidavit filed with the German court as follows:

- The inlet filtration of Bair Hugger blowers does not prevent contamination. The majority of blowers cultured were contaminated with bacteria.
- Some forced air blowers emit large numbers of 0.3-0.5 micron particles. Up to 50 million particles per hour blowing from the hoses have been measured.
- The warm, dry interior of forced air blowers does not kill all pathogens. (Annex O)

In 2008, after clinicians throughout the UK were informed by Dr. Augustine, the inventor of Bair Hugger therapy, of the risk of contamination created by FAW, Arizant's CEO, Gary Maharaj, wrote a widely disseminated letter, quoting a finding by NICE that "FAW systems are naturally built to eliminate bacteria." (Annex P). One can only assume that Maharaj knew the statement was inaccurate; he had been informed of the contamination problem in 2007. Moreover, a device with a filtration efficiency of 61.3% is barely built to reduce bacteria, much less "to eliminate bacteria."

In March 2010, Dr. Scott Augustine wrote Maharaj and Arizant's Chief Regulatory Officer, David Westlin, urging them to inform the FDA and European regulators of the contamination risk created by Bair Hugger blowers and to cease the fraudulent claims of HEPA filtration. (Annex Q). Arizant did not respond.

Arizant continues to make the same misrepresentations via the Internet. In a document on its website entitled, "Facts About Forced-Air Warming." Arizant purports to "address some inaccuracies about forced-air warming that makers of competing technologies are promoting." Once again, Arizant claims that Bair Hugger filtration is "high efficiency" (HEPA). (Annex R)

C. Regulatory consequences

As described in 21 CFR 807.81(a)(3), a new 510(k) application is required for changes to an existing device where the change could significantly affect the safety or effectiveness of the device. Arizant's failure to file a new 510(k) after downgrading its filter to 61.3% efficiency violates this standard.

The FDA requires that every modification to a device be reviewed by appropriate personnel in accordance with the 21 CFR 820 Quality System regulations. If the modification is determined to be insignificant, the decision must be documented with supporting data in the master file. If it is significant, a new 510(k) must be filed. Given the consequences of the degradation of the Bair Hugger filter, the change certainly required filing a new 510(k).

A proper analysis would have followed the protocols set forth in ISO Standard 14971, entitled "Medical devices — Application of risk management to medical devices." Sec. D.2.2.3 cites a situation exactly like that presented by Bair Hugger as

an example of systemic fault:

> inadequate environmental control, or a breakdown in environmental control systems, leads to contamination with a toxic substance or an infectious agent.

Sec. D.3 describes how to evaluate the level of risk. Given the often-catastrophic consequences of surgical infections, the following standard seems to apply:

> [F]or significant hazards, that is, hazards which could inflict harm of high severity…no level of exposure can be identified that corresponds to a risk so low that there is no need to bother about it. In such cases, the risk estimate should be made on the basis of a reasonable worst-case estimate of probability.

Since it did not file a new 510(k), Arizant either failed to perform a risk analysis at all or it performed the analysis inadequately. A calculation of Arizant's culpability should be influenced by Arizant's 1997 admission that "air blown intraoperatively across the surgical wound may result in airborne contamination" as well as by any financial gain that Arizant enjoyed as a result of the safety degradation.

Such culpability, in fact, could extend to illegal adulteration. Medical devices are subject to the adulteration provisions of Sec. 501 of the Food, Drug and Cosmetics Act. Specifically, Sec. 501(c) states that a device is adulterated if its quality falls below that which it purports or is represented to possess. Arizant represented to the FDA and to the public that the Model 750 Bair Hugger blower protected surgical patients from bacterial contamination with HEPA filtration. It then knowingly failed to meet that standard. Despite the degradation of safety, Arizant continues to claim high efficiency filtration. The FDA may assess monetary penalties for violations of Sec. 301(a) of the Act (the introduction or delivery "into interstate commerce of any … device … that is adulterated or misbranded") of up to $15,000 for each violation up to a total of $1,000,000.

D. Recommendations

Arizant should be required to restore the inlet filtration in its Bair Hugger blowers to HEPA standards. As noted above, an additional filter that conforms to ASHRAE Standard 170 should be installed distally at the hose end. Neither action, however, deals with the immediate issue: tens of thousands of Bair Hugger blowers that have become internally contaminated with pathogens because of the inadequate inlet filtration. All such blowers should be recalled from the field and be internally decontaminated before being put back into service.

III. Destruction of Laminar Flow protection

A. Importance of Laminar Flow

According to a study cited by the Centers for Disease Control, laminar flow ventilation reduces SSIs by more than 50%--from 3.4% to 1.6%. [xvii] In a study of 435 patients undergoing Austin Moore hemiarthroplasty, the rate of re-operation for all indications in the non-laminar airflow theater group was four times greater than in the laminar airflow group. Similarly, the use of laminar flow reduced infection rates after posterior spinal fusion.[xviii]

Laminar flow is especially important in orthopedic surgery—where a single airborne bacterium has been shown to be able to infect implanted foreign material such as a prosthetic knee or hip.[xix] For that reason, current CDC recommendations include performing orthopedic implant operations under laminar flow.[xx]

Similarly, a 2003 article by Farhad Memarzadeh, PhD, PE, chief of technical resources in the Division of Engineering Services at the National Institutes of Health, concluded:

> Systems that provide laminar flow regimes represent the best option for an operating room in terms of contamination control, as they result in the smallest percentage of particles impacting the surgical site.[xxi]

B. Impact of FAW on Laminar Flow

Observations during the above-cited research lead to concern about the impact of the "waste" hot air emitted from FAW blowers—particularly on laminar flow ventilation during ultra-clean surgery. In general, a FAW blower produces 1,000 watts of heat energy per hour. Only about 50 watts are transferred to the patient; the rest escapes from under the surgical drape near the floor, then rises through the dirty air located near the floor and into the laminar flow. The air then cools and dumps the contaminated air into the sterile field. (A visualization of this appears in the video attached as Annex M)

Similarly, this phenomenon can be observed in the blog[xxii] and YouTube videos[xxiii] posted by Drs. Reed and McGovern – orthopedic surgeons and researchers in Northumbria, UK. In these experiments, they used "neutral buoyancy" bubbles (small soap bubbles filled with a mixture of air and helium which is adjusted to produce neutral buoyancy), to show the air currents created by rising waste heat from FAW.

Additional research regarding the destruction of laminar flow protection by waste heat from FAW blowers includes the following:

1.) "Forced Air Warming versus Conductive Fabric Warming – An Evaluation of Conventional (non-laminar, positive pressure) Operating Room Ventilation Disruption," a recent study in submission for publication in the *Annals of Surgery*, was authored by a team including myself and Drs. M. Reed and P McGovern. The effect of waste heat was studied in a conventional (non-laminar, positive pressure) operating room ventilation environment. FAW was compared with conductive fabric warming (CFW), with and without a surgeon by the table. Tracer smoke was introduced near the floor under the operating table. The degree of ventilation penetration and disruption was determined by the percentage of smoke detected in the air directly above the surgical site. The results:

* With a surgeon present, forced air warming (FAW) on "high" heat resulted in a large increase in the percentage of tracer-laden air from under the operating table detected at the surgical site versus FAW ambient control (63.0% v 6.9%).

* With a surgeon present, conductive fabric warming (CFW) on "high heat" resulted in no increase in the percentage of tracer-laden air detected at the surgical site versus CFW ambient control (4.9% v 6.1%).

* The use of forced air warming was found to generate sufficient waste heat to disrupt conventional OR ventilation and mobilize tracer contaminated air from under the table upwards and into the surgical site. Detected particle counts showed that in the presence of a single surgeon, the waste heat from FAW on "high" could mobilize sufficient quantities of tracer-laden floor air, so that more than half of the air directly above the surgical site consisted of potentially pathogenic floor air. (Annex S)

2.) "Forced Air Warming versus Conductive Fabric Warming – An Evaluation of Laminar Operating Room Ventilation Disruption" a recent study in submission for publication in the *British Journal of Orthopedics*, was authored by a team including myself and Drs. M. Reed and P McGovern. We compared the effects of two patient warming modalities classified as having "low waste heat load" (conductive fabric warming - "CFW") and "high waste heat load" (forced air warming – "FAW") on laminar ventilation performance. Neutral buoyancy soap bubbles ("bubbles") were used to visualize airflows and particle counts of tracer smoke were performed 15 cm above the surgical site to quantitatively assess tracer mobilization into the surgical site. The results:

* Vented waste heat from FAW use at 43°C created warm-air convection currents that mobilized tracer particulate upwards against the downward laminar flow and into the surgical site, as indicated by bubbles.

* With no surgical staff, the use of FAW at 43°C resulted in a ≈30-fold increase in particle counts at the surgical site versus controls.

* With a surgical staff present, the use of FAW at 43°C resulted in a ≈90-fold increase versus controls.

* CFW use at 43°C produced minimal waste heat and had no effect on airflow currents or particle counts at the surgical site versus controls.

* Conclusion: The use of FAW generated sufficient waste heat to form convection currents that disrupted laminar ventilation performance and mobilized tracer contaminated air into the surgical site from high pathogenic-risk locations near the floor and under the drape. Bubbles showed the sheltered space between the surgeon's body and operating table as the primary area these convection currents form. (Annex T)

3.) In a abstract submitted to the American Academy of Orthopedic Surgeons 2011 annual meeting by Drs. M Reed and P McGovern, FAW was compared with conductive fabric blankets (CFB) in its effect on laminar flow ventilation. Airflow was visualized with neutral buoyancy bubbles introduced under a torso warming blanket at the head end of the table. The findings:

* There was no contamination of the surgical site when using CFB.

* A significant increase in laminar ventilation disruption was detected using Poisson regression for FAW v CFB with no ether screen (6 v 0 bubbles over the surgical site; $p<0.01$).

* A very significant increase in laminar ventilation disruption was detected using Poisson regression for FAW v CFB with a half height ether screen (146 v 0 bubbles over the surgical site; $p<0.01$).

* FAW disrupts laminar ventilation performance and mobilized potentially contaminated under-drape air against the downward laminar flow and into the surgical site.

C. Arizant's knowledge of the risk

In October 2009, at the annual meeting of the American Society of Anesthesiologists held in New Orleans, Arizant was informed of the disruption of laminar flow protection caused by the waste hot air exhausted by Bair Hugger blowers. The video (Annex M) was watched several times by Arizant Chief Scientist Al Vanduren, whose comments included, " I didn't know that," and "I didn't think the air would do that." Other Arizant executives watched the video as well. (Affidavit of Scott Augustine, Annex F)

D. Arizant's response

Ignoring its own observations and scientific evidence to the contrary, Arizant's webite assures clinicians that the contaminated air cannot reach the surgical site because,

"Air velocity within the operating theatre is many times stronger than that of the forced-air warming blanket." (Annex R)

Arizant has even begun running advertisements in UK medical publications, further attempting to obfuscate the issue. (Annex U). In response to concerns that waste hot air from Bair hugger blowers disrupts the protection of laminar flow, Arizant's advertisement states:

> While simple logic makes it clear that forced air warming has no impact on laminar conditions, science also supports this. A forced air warming blanket delivers less than one percent of the airflow of a laminar flow system and therefore is unable to affect laminar flow ventilation systems." (Emphasis added) (Id.)

If disruption of laminar flow were a mere marketing issue, Arizant's misdirection might be acceptable, perhaps even clever. The issue, however, is patient safety, and Arizant has an obligation to be honest rather than clever. A comparison of airflow is irrelevant. The fundamental issue is waste heat, not waste air. The physics are simple: heat rises. Almost all of the 1000+ watts of heat/energy generated by the Bair Hugger blower escapes near the floor, mixes with dirty air, rises into the laminar flow and falls into the sterile field. (Annexes M and T).

E. Additional evidence

Other recent evidence adds to the concerns about airborne contamination during surgery. For example, in one of a series of articles published in *Interface*, the Journal of the UK's Royal Society, researchers wrote:

"In hospital operating theatres, the convective flows could spread infection and pose a real threat to the outcome of surgery." [xxiv]

Finally, a Ph.D. dissertation published by University Of Leeds engineering student Katherine A. Roberts under the supervision of surgical air-quality expert Prof Clive Beggs investigated the likelihood of airborne dissemination of *Clostridium difficile*. She stated that " the aerial dissemination of *C. difficile* in hospitals contributes to the spread of disease, accompanied by the contact route." [xxv]

Her conclusion:

> The evidence for the aerial dissemination of *C. difficile* discussed in this thesis suggests that the high rates of CDI

> experienced in UK hospitals and around the globe may be due to the aerial dissemination route increasing environmental contamination. Id.

Although the evidence that FAW spreads *C. difficile* is far less developed than evidence regarding other pathogens, Roberts's conclusion underlines the importance of protecting surgical patients from aerosolized bacteria.

E. Recommendations

Unlike the previous issues raised in this Report, the destruction of the protection of laminar flow ventilation by waste heat has no easy solution. Waste heat is an inescapable by-product of FAW. At a minimum, therefore, the FDA should require that the labels and instructions for FAW blowers contraindicate their use in orthopedic implant and other ultra-clean surgeries employing laminar flow protection.

IV. Violation of reprocessing standards

A. Contaminated blowers placed in hospitals

Of the tens of thousands of Bair Hugger blowers loaned (or leased without charge) to US hospitals, many thousands have been refurbished or remanufactured by Arizant. That is, after several years of use, the units were returned to Arizant for repair, were refurbished, then returned to the field for use in other hospitals with their serial numbers prefaced with an "R." (Affidavit of Dr. Scott Augustine, Annex F)

Remanufacturing and refurbishment at Arizant includes replacing filters and hoses, checking electronics and cleaning the exterior of the blower as needed. The interior air-flow path of the blower, however, is not cleaned. In fact, without complete disassembly of the device, it cannot be cleaned. Id. The obligation of a re-manufacturer, however, is to return the medical device to its original specifications. 21 CFR 820 In this case, it certainly requires that Arizant clean the contaminated interior of the devices.

Upon original placement in the field, the air-flow path of a Bair Hugger blower is clean and uncontaminated. As studies funded by Arizant have shown, such pristine blowers do not add to the bacterial load in operating theatres. However, the research cited herein establishes that after significant use, the airflow paths of the blowers become heavily contaminated with pathogens.

Arizant places refurbished, but contaminated, FAW blowers in operating theatres as if they were new. The hospitals' biomedical engineers, having no way to check the cleanliness of the sealed interior of the blowers, certify them for use. In this manner, pathogenic contamination from one hospital can spread to others.

B. Recommendation

All refurbished "R" Bair Hugger blowers should be recalled from the field and be internally decontaminated. If internal decontamination is not possible, use of refurbished blowers should be prohibited.

V. Failure to Meet FDA Reporting Obligations

A. Arizant's failure to file an MDR

The FDA requires that a manufacturer report via the Medical Device Reporting (MDR) system when the manufacturer becomes aware of information reasonably suggesting that one of its marketed devices has malfunctioned and that such malfunction has or would be likely to contribute to a serious injury. 21 CFR Sec. 803.3(q) A malfunction is a failure of the device to meet its performance specifications or to otherwise perform as intended. 21 CFR Sec. 803.3(m) A malfunction is reportable if it compromises the device's therapeutic effectiveness or if it could contribute to a serious injury or a significant adverse device experience. Id. A device may have contributed to such an event, among other reasons, because of improper or inadequate device design. 21 CFR Sec. 803.3(d) A manufacturer has become aware of a reportable event when a person with management or supervisory responsibilities becomes aware of the event from any source. 21 CFR Sec. 803.3(c)

Even if unaware previously, Arizant learned that its blowers spread pathogenic contamination no later that October 2007, at the annual meeting of the American Society of Anesthesiologists. Arizant learned that waste heat from its blowers destroys the protection of laminar flow and dumps dirty air into the surgical field no later than October 2009, again at the same annual meeting. All of these facts, as well as published peer-reviewed evidence, were reiterated in Dr. Augustine's letter to Arizant CEO Gary Majaraj dated April 2, 2010.

Despite this information, Arizant has not filed an MDR or provided any other information to the FDA. Presumably, Arizant will defend its inaction by noting that no hospital has reported a surgical infection traced specifically to a contaminated Bair Hugger blower.

Such, however, is not the standard. As noted above, a malfunction is reportable if it could contribute to a significant adverse experience. Destroying the

protection of a surgical laminar flow system is a significant adverse device experience even if no infection occurs. In orthopedic implant surgery contamination by a single bacterium can lead to infection.[xxvi] With such a risk, Arizant's awareness that Bair Hugger systems do not meet their own filtration specifications and blow millions of particles into the surgical field certainly created a reporting obligation. The failure to report is a prohibited act, and renders the device misbranded. FDCA §§ 301(q)(1), 502(t), 21 U.S.C. §§ 331(q)(1), 352(t)

Given that the FDA cited Arizant with Form FDA 483 in January 2010 for failing to properly report injuries, the company should be acutely aware of its responsibilities under the MDR system. (Annex V)

B. Recommendation

Arizant should incur the full penalties that can be levied by the FDA for its repeated failure to report risks to patient safety.

Conclusion:

I request that the FDA carefully review the evidence attached and fully investigate the issues raised. If the FDA confirms the accuracy of the facts and analysis I have provided, I ask that the FDA act quickly to protect vulnerable surgical patients, particularly those undergoing orthopedic or other ultra-clean surgery.

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Kentucky
Epidemiologic Notes & Reports

Cabinet for Health and Family Services
Department for Public Health
Division of Epidemiology and Health Planning

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Acinetobacter Infections among Hospitalized Patients in Kentucky – 2006

Emphasis on environmental cleaning and isolation precautions may prevent future outbreaks

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CDR Doug Thoroughman, Ph.D., CDC Career Epidemiology Field Officer, Kentucky Department for Public Health

Background

Acinetobacter baumannii is a gram negative rod commonly found in the environment, including the soil, food, and water. Although *Acinetobacter* infections caused only about 7% of Intensive Care Unit (ICU) pneumonias in 2003, they are an increasingly common cause of nosocomial and ICU pneumonia (1). In September 2006, two Kentucky hospitals in different communities independently reported *Acinetobacter* outbreaks to the Kentucky Department for Public Health (DPH) within one week of each other. This report describes the outbreak investigation performed at these two facilities.

Investigation Methods

On September 29, 2006, DPH received notification of an *Acinetobacter* outbreak among patients in Hospital A. On October 3, the Centers for Disease Control and Prevention (CDC) notified DPH of a cluster of patients in a second facility (Hospital B), after being contacted directly by Hospital B infection control staff (CDC refers such state-based inquiries back to the State health department). An increase in case-patients from a baseline of approximately 1-2 per month to approximately 15 per month was reported for the months of August through October in Hospital A, and April through October in Hospital B. Patients were diagnosed with *Acinetobacter* based on wound, blood, sputum, urine, or bone culture obtained after a change in the patient's clinical status occurred.

A total of 102 people were confirmed positive at the two facilities by clinical culture (30 in Hospital A and 72 in Hospital B). A CDC investigation was requested by DPH to provide additional personnel to assist with the large workload that would be generated by chart reviews, infection control compliance assessments, environmental evaluations, and lab testing inherent in a hospital investigation of this nature. Suzanne Beavers, MD, (the author of this article and Kentucky's Epidemic Intelligence Service (EIS) officer) began the investigation in early October, 2006 and subsequently led a team of four CDC investigators who arrived on October 30th. The primary goals of the investigation were to perform a case-control study to find risk factors associated with *Acinetobacter* infection, to examine infection control practices at the hospitals involved, and to look for ways to decrease transmission possibilities and incidence of infection at the two facilities.

A case was defined as a patient hospitalized during August 1-October 31, 2006 (Hospital A) or April 1-October 31, 2006 (Hospital B) who developed a positive culture for *Acinetobacter* on a clinical specimen. Patient charts were reviewed in order to evaluate potential risk factors such as admitting service, unit on admission, past medical history, surgeries during hospitalization, and need for ventilation or an invasive intravascular device. A control population was selected from patients without

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March Notes & Reports.....

Acinetobacter who were hospitalized greater than or equal to the mean length of hospitalization for cases prior to obtaining the first positive culture. Isolation room practices were also observed in order to determine the level of compliance among hospital staff for contact and isolation precautions. In order to evaluate cleaning of high touch areas, a fluorescein compound visible with Wood's lamp was placed in patient rooms. The rooms were checked on subsequent days to determine if the fluorescein compound had been removed by daily cleaning, or cleaning of the room after patient discharge from the room. Environmental samples of high-touch areas in rooms containing patients positive for *Acinetobacter* were also taken.

Results

The mean age of cases was 43 years in Hospital A and 46 years in Hospital B. At Hospital A, 48% of cases were female; 25% of cases were female in Hospital B. The majority of patients (51.7% in Hospital A, 62.5% in Hospital B) cultured positive from a respiratory specimen. During the initial analysis, admission to a surgery service was associated with *Acinetobacter* infection, as was ICU admission. Artificial ventilation was also associated with a positive culture. The majority of patients (81.5% at Hospital A, 70.8% at Hospital B) had multi-drug resistant (MDR) *Acinetobacter* on culture (Figure 1).

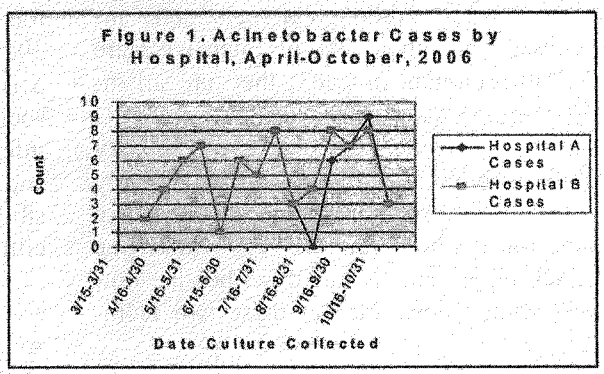
Room observations revealed several instances in both facilities where isolation protocols were violated. Providers were occasionally observed entering the rooms without washing their hands. Providers occasionally entered the room without using barrier precautions such as gowns. Providers also were observed exiting the room without performing adequate hand washing.

Evaluation of the environmental cleaning focused on several high-touch areas in the room. Fluorescein staining was consistently found in high-touch areas in the room after daily cleaning. Fluorescein could also be seen in high-touch areas following cleanings performed after a patient was discharged from the room.

Swabs performed by the hospitals prior to the investigative team's arrival did not reveal a point source of infection or one focus of environmental contamination. However, quantitative environmental testing at the two facilities is ongoing.

Hospital A closed its surgery ICU on the day of the team's arrival for thorough cleaning and decontamination and subsequently closed a second ICU for additional cleaning. In addition, enhanced isolation and decontamination procedures were also instituted throughout the hospital. Hospital A has subsequently reported lower incidence rates since October. Hospital B increased emphasis on following isolation precautions and has used fluroescein to evaluate and increase the importance of cleaning high-touch area, noting a decrease in cases as of February, 2007.

Figure 1. *Acintobacter* cases by hospital, April-October 2006



Discussion

Acinetobacter baumannii is an increasing source of nosocomial infection nationwide. *Acinetobacter* species may cause pneumonia, wound infections, urinary tract infections, or bloodstream infections. Risk factors for *Acinetobacter* infection include recent surgery, admission to an ICU, need for antibiotics during hospitalization, and admission to a ward where other infected patients reside.

Results of the present investigation indicate the need for environmental cleaning staff education on the importance of cleaning high-touch areas. Areas such as bed rails, monitors, and door knobs are likely to be touched by patients and caregivers, and could be a source of spread of the implicated bacte-

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ria.

Acinetobacter species demonstrate the ability to survive for long periods in the environment. Previous researchers were able to culture *Acinetobacter* from a bedrail nine days after an infected patient was discharged from the room. Therefore, environmental contamination is often an important source of transmission of the organism. Previous outbreaks have found items such as common-use respiratory medications, ventilators, Bair Hugger temperature management units, mattresses, cellular phones, and curtains to be reservoirs of infection. Emphasis on environmental cleaning and observation of isolation precautions are consequently of particular importance in control of *Acinetobacter* outbreaks.

Another factor that has been of importance in the emergence of *Acinetobacter* nosocomial infections is the intrinsic antibacterial resistance of *Acinetobacter* and its ability to quickly acquire new resistance mechanisms. In fact, strains of *Acinetobacter* resistant to all antimicrobials have been isolated. *Acinetobacter* species are readily able to incorporate new genetic material into their DNA. This ability leads to the rapid acquisition of bacterial resistance, even from other types of bacteria such as *Pseudomonas*. The need for frequent use of antimicrobials in intensive care settings is also associated with the rapid acquisition of resistance.

Several methods have been used to control previous outbreaks. When a common source such as a ventilator is identified, cleaning the source properly or preventing patient exposure to the source has been effective in stopping the outbreak. Frequently, however, a common source is not identified. In these cases, increased emphases on environmental cleaning, use of active surveillance, and cohorting patients have been effective in halting outbreaks. Unit closure and environmental decontamination have also been beneficial.

Closing Notes

The outbreak investigations at the two facilities demonstrated the need for reinforcement of isolation precautions and enhanced environmental cleaning. Further analysis of data will continue in order to identify other risk factors and control methods to assist in preventing future outbreaks. Additional work will continue with the hospitals to make recommendations for environmental cleaning as required.

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World Tuberculosis Day – March 24

Despite diligent intervention efforts, TB disease remains a global threat

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Melissa Dalton Hopkins, Social Work Consultant/ Health Planner, Kentucky TB Control Program

Condensed from CDC National Center for HIV, STD, and TB Prevention, Division of TB Elimination

Each year, World Tuberculosis (TB) Day is recognized on March 24th. This annual event commemorates the date Robert Koch announced his discovery of the bacillus that causes TB. Around the world, TB programs, non-governmental organizations, and others take advantage of the increased interest and awareness that World TB Day generates concerning the international health threat that the disease presents. It is a day to recognize the collaborative efforts of all countries involved in fighting TB. TB can be cured, controlled, and with diligent efforts and sufficient resources, eventually eliminated.

In 1993, 404 active TB cases were reported in Kentucky, with a case rate of 10.7 cases per 100,000 population. Since 1993, TB case rates have been declining, suggesting that the nation is recovering from a resurgence of TB that occurred in the mid-1980s, and is back on track toward TB elimination. While the decrease in TB case rates is encouraging, the facts about TB continue to be alarming:

- TB continues to kill more people in the world each year than any other infectious disease.
- TB cases continue to be reported in every state.
- Multiple Drug-Resistant TB (MDR-TB) cases

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continue to be reported in almost every state.
- Extreme Drug-Resistant TB (XDR-TB) has emerged.
- An estimated 10 to 15 million persons in the U.S. are infected with *Mycobacterium tuberculosis*.
- Without intervention, approximately 10% of the 10 to 15 million persons infected in the U.S. will develop TB disease at some point in life.
- Certain other medical conditions increase the risk that a person with TB infection will develop TB disease (e.g. HIV, diabetes mellitus, cancers of the head and neck, jejunoileal bypass, solid organ transplantation, and other immunocompromising conditions).
- HIV infection is the strongest risk factor for progression from TB infection to TB disease. Approximately 50% of HIV-infected persons who become TB infected will develop disease within the first two years of exposure.

Where Are We Now?

TB remains a health threat to people around the world. Among infectious diseases, TB remains the second leading killer of adults in the world, with more than 2 million TB-related deaths each year. In addition to MDR-TB, the emergence of XDR-TB creates a greater and more deadly challenge of this disease. Whereas MDR-TB is drug resistant TB to two or more first line TB drugs, XDR-TB is defined by the World Health Organization (WHO) as TB that is resistant to the two main first line TB drugs, isoniazid (INH) and rifampin (RIF), as well as three of the six main classes of second line drugs. Poor treatment outcomes (patient not responding effectively to treatment) or failed treatment (patient not completing treatment or was lost to follow-up) are the largest contributing factors to the development of MDR-TB and XDR-TB. However, drug resistant strains are transmitted from person-to-person. Until TB is controlled, World TB Day will not be a celebration, but a valuable opportunity to educate the public about the devastation that TB can spread, and how it can be stopped.

TB in Kentucky

Reported cases of TB in Kentucky have reached a historic low. In 2006 there were 84 TB cases reported for a statewide rate of approximately 2.0 cases per 100,000 population. This rate places Kentucky well below the national TB case rate of 5.1 cases per 100,000 population, and below the state objective set in 1999 of reducing the verified TB case rate to 3.5 per 100,000 population. In 2005, the Kentucky TB Control Program reported 124 cases compared to 127 cases in 2004, 138 cases in 2003, and 146 cases in 2002. This case reduction illustrates the hard work and dedication of TB Control staff at the local health departments.

The future of TB Control in Kentucky

The lowering of case numbers is not, however, an indication that the war on TB has been won. Diligent efforts to identify and treat persons with TB infection that are at high risk for developing TB disease is the key to the continued reduction of incidences of TB disease in Kentucky. In addition, ensuring successful treatment outcomes to those with active disease is the main method for preventing MDR-TB and XDR-TB. To date in 2007, there have already been more than 20 active TB cases reported, a high case number for this early point in the year. To prevent resurgence, staff and resource levels must be maintained to allow Kentucky officials to have the tools required to continue working toward elimination of this most persistent disease.

Sexually-Transmitted Disease Update for Kentucky

Advancements in screening programs result in early detection

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Although sexually transmitted disease (STD) rates in Kentucky are not among the highest in the nation, they continue to be the most frequently reported of all communicable diseases statewide. *Chlamydia trachomatis* was the most frequently reported communicable disease in Kentucky in 2005, with 8,351 reports and an attack rate of 201.4 per 100,000 population. Gonorrhea was the second most frequently reported communicable disease in 2005 with 2,935 reports and a rate of 70.8 per 100,000 population. The same trend for these two diseases continued in 2006, as reported chlamydia

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cases increased 7.1% to 8,940 cases. Gonorrhea increased 11.1% with 3,277 reports.

Data released in November 2006 by the Centers for Disease Control and Prevention (CDC) revealed that Kentucky officially ranked 44th nationally in chlamydia and 31st in gonorrhea rates per 100, 000 population in calendar year 2005. *Chlamydia trachomatis* is recognized as one of the most prevalent and potentially harmful STDs today. Men, women and infants are affected, but women bear a greater burden from infection, which is often asymptomatic. Infection in women can seriously compromise present and future reproductive health and may result in ectopic pregnancy, salpingitis, and pelvic inflammatory disease. Neonates of mothers infected with chlamydia and/or gonorrhea may develop an eye infection (opthalmia neonatorum), and neonates of mothers infected with chlamydia could develop pneumonia within the first two months of birth. Many improvements in the laboratory identification of chlamydia and gonorrhea within the past decade have enabled aggressive screening programs to be initiated in each state to identify women with uncomplicated chlamydia and gonorrhea infection. Early detection can enable treatment before complications and debilitating sequela associated with these infections occur. The target population for the screening programs has consisted of women of child bearing age seeking contraceptive, prenatal, STD, cancer screening, and other health services through public and private care facilities. The latest types of tests, known as nucleic acid probes, are more sensitive and specific, and enable the provider to screen patients for both chlamydia and gonorrhea from the same specimen collected by swab from the cervix or from a urine specimen. As a result of the newer testing procedures, there has been a significant decrease in the number of false negative results and an increase in the number of true positive results among persons screened.

Syphilis cases reported in calendar year 2006 totaled 188 compared to 129 cases in 2005. Included in this total were 73 patients with primary or secondary stage disease and 36 patients with early latent stage syphilis disease. The primary, secondary, and early latent stages of syphilis are collectively known as early syphilis because patients have been infected for one year or less and, unless treated, potentially could spread infection to a sexual partner. The 109 patients reported with early syphilis in 2006 was a 34 case (45.3%) increase over 75 early syphilis cases reported in 2005. Included in the 109 early cases were 97 males and 12 females for a male to female ratio of 8:1. Syphilis case reporting is influenced by outbreaks that occur among populations at high risk for acquiring STDs. Over the past four years, a disproportionate number of early syphilis cases have been found in men who have sex with men. In calendar year 2006, 25 Kentucky counties reported one or more patients with early syphilis. Jefferson County reported the most cases with 52 reports, which included 49 males and 3 females. Fayette County had the second highest number of reports with 20 cases, all of whom were males.

Physicians and other healthcare professionals play a critical role in treating and preventing the spread of sexually transmitted diseases. CDC recently released a publication entitled *Sexually Transmitted Diseases Treatment Guidelines, 2006* to assist healthcare professionals in their efforts to diagnose and treat STDs. Requests for the 2006 treatment guidelines can be made through the Kentucky STD Program at (502) 564-4804. The guidelines are also available online at: http://www.cdc.gov/std/treatment/2006/clinical.htm.

Additionally, physicians and healthcare providers are urged to report STDs to their local county health department or to the STD Program at the Kentucky Department for Public Health. The Cabinet for Health and Family Services under 902 KAR 2;020 requires primary, secondary, early latent and congenital syphilis to be reported within 24 hours by fax at (502) 564-5715 or phone (502) 564-4804. Other STDs such as chlamydia, chancroid, gonorrhea, granuloma inquinale, lymhogranuloma venereum, late latent syphilis, and late manifest syphilis are to be reported within five business days. The Kentucky Reportable Disease Form (EPID 200-Rev. May/06) can be accessed online at: http://chfs.ky.gov/providers/ or from the Kentucky STD Program at (502) 564-4804.

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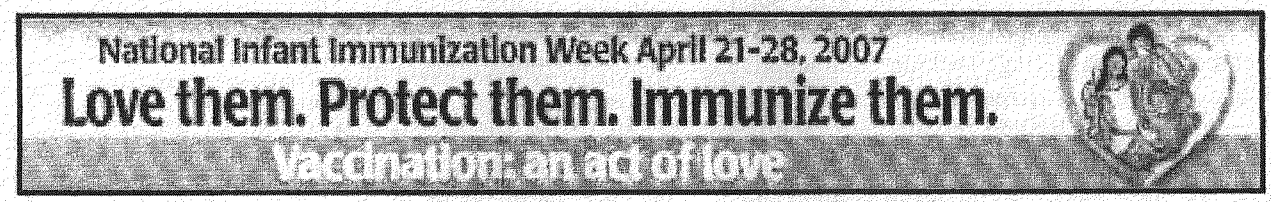


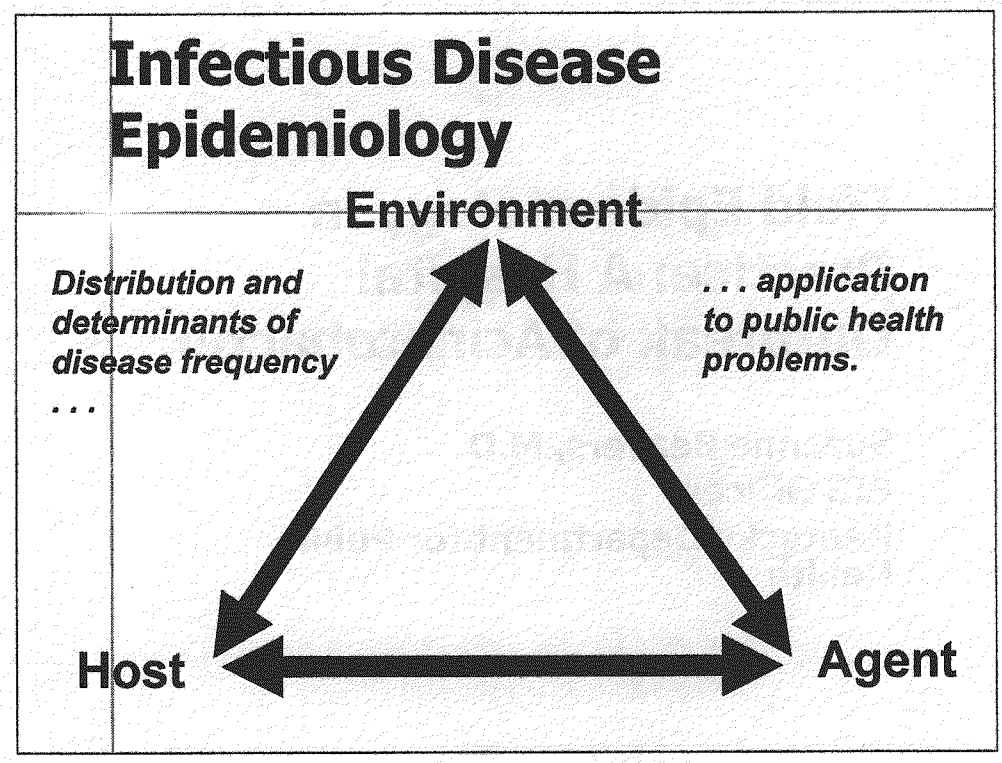
Upcoming Articles in *Epi Notes*!

- **Rabies Update**
- **National Infant Immunization Week (April 21-28, 2007)**
- **National Medical Laboratory Professionals Week (April 23-27, 2007)**

Field Epidemiology in Practice: A Hospital Outbreak of Acinetobacter

Suzanne Beavers, M.D
EIS Officer
Kentucky Department for Public Health

Good evening. My name is Suzanne Beavers. Tonight I'll discuss a recent investigation we performed into a hospital Acinetobacter outbreak. I'd also like to highlight the ten steps taken during a investigation of a healthcare outbreak and some of the differences between a hospital outbreak and other types of outbreaks.



As you know, epidemiology is the study of the distribution and determinants of disease frequency in populations, and the use of this information to address public health problems. **ADVANCE**

Epidemiologists use a conceptual framework called the epidemiologic triangle to describe relationships among hosts (or diseased persons), agents (or infecting organisms) and the environment (the setting in which transmission occurs). This model helps us to consider each factor's role in the spread of disease.

We then conduct studies to evaluate these relationships so we can alter them to our advantage. Examples of this include:

making a host less susceptible to infection by vaccination,

removing people from an environment that promotes disease transmission,

or rendering an infectious agent less virulent through judicious use of antibiotics.

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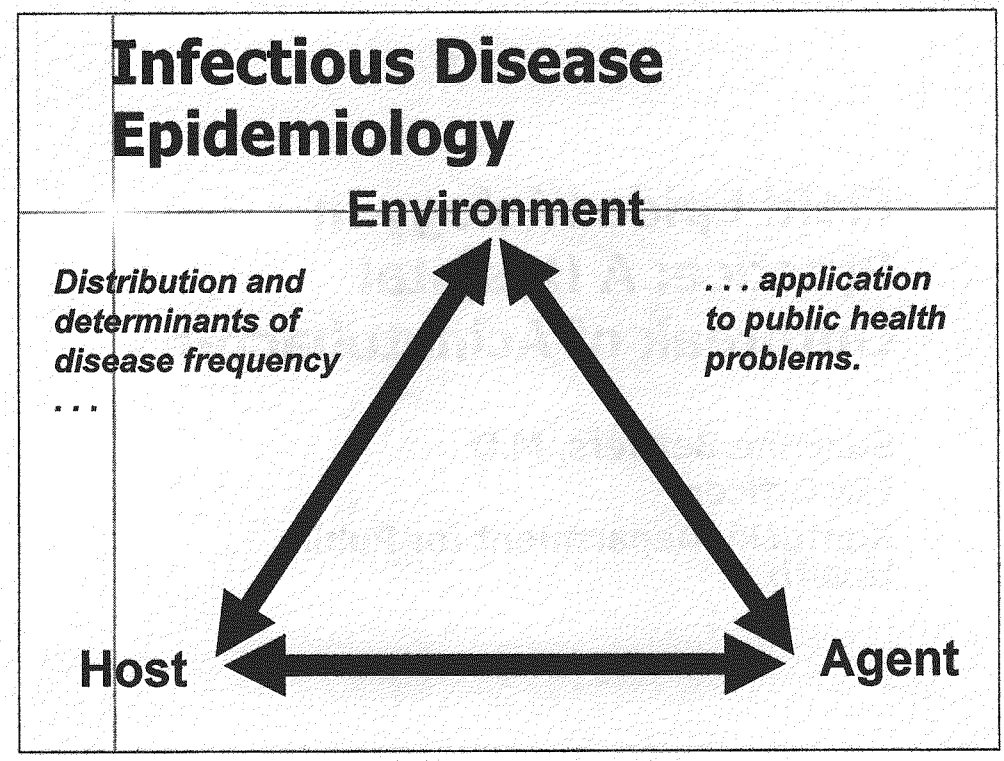

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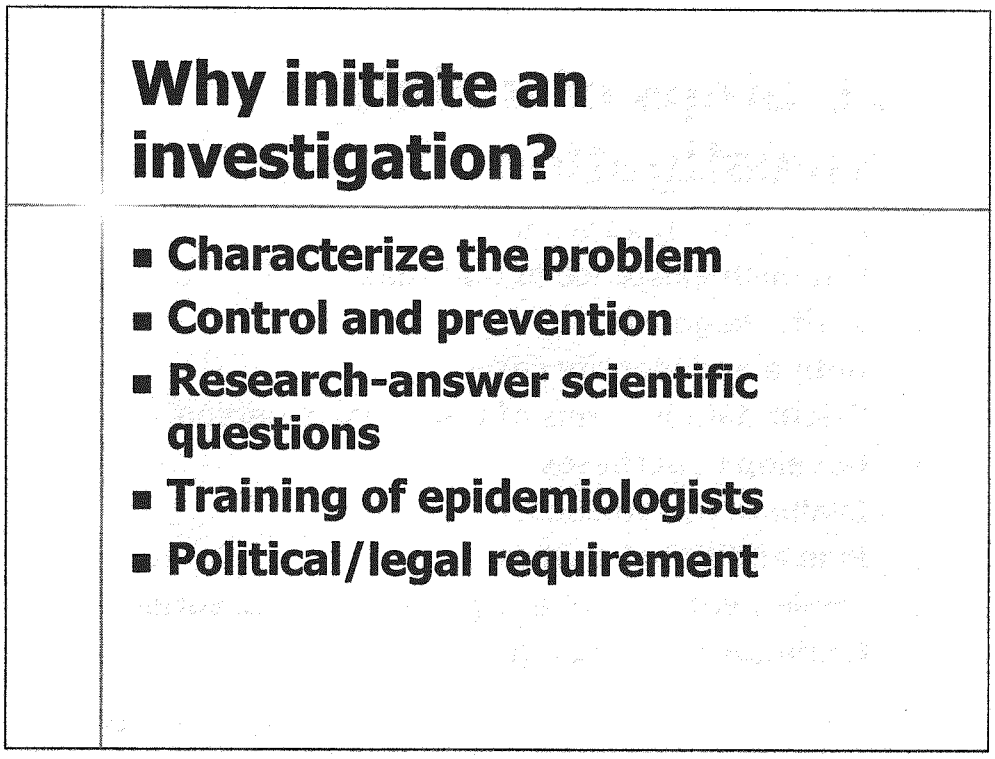


Of course, the most obvious reason to do an investigation is because it is your job or legal requirement to do so. However I've referred to this in the last bullet because there are several better reasons to do an investigation. The most immediate reason is to characterize the problem. Once we learn more about the problem, we may be better able to control it and prevent it from occurring in the future. Another reason to perform a field investigation is to conduct more formal research. Thereby, we may learn more about the problem being investigated. Perhaps our field investigation will lead to knowledge of a new risk factor for a particular disease. Finally, even if the problem or disease has been studied many times, an investigation enables us to train new epidemiologists and improve our skills of investigation.

10 Steps of a Field Investigation

1. Prepare for field work
2. Establish existence of outbreak
3. Verify diagnosis
4. Define and identify cases
5. Orient data in terms of time, place, person
6. Develop hypotheses
7. Evaluate hypotheses
8. Plan additional studies
9. Implement control and prevention measures
10. Communicate findings

Adapted from Field Epidemiology ed. Gregg MB

Having said that, there are steps an investigator should take to make things go more smoothly in the field.

I've listed 10 steps here for reference. Keep in mind that there are variations on how the 10 steps are written and ordered, but all variations cover the same basic concepts. I won't spend much time on them now, as I'll be going through them in the outbreak example.

The list begins with things that seem obvious like "establishing the existence of an outbreak" and ends when an outbreak has been controlled and results have been disseminated to interested parties.

These steps can take days to complete, or months, depending on the outbreak.

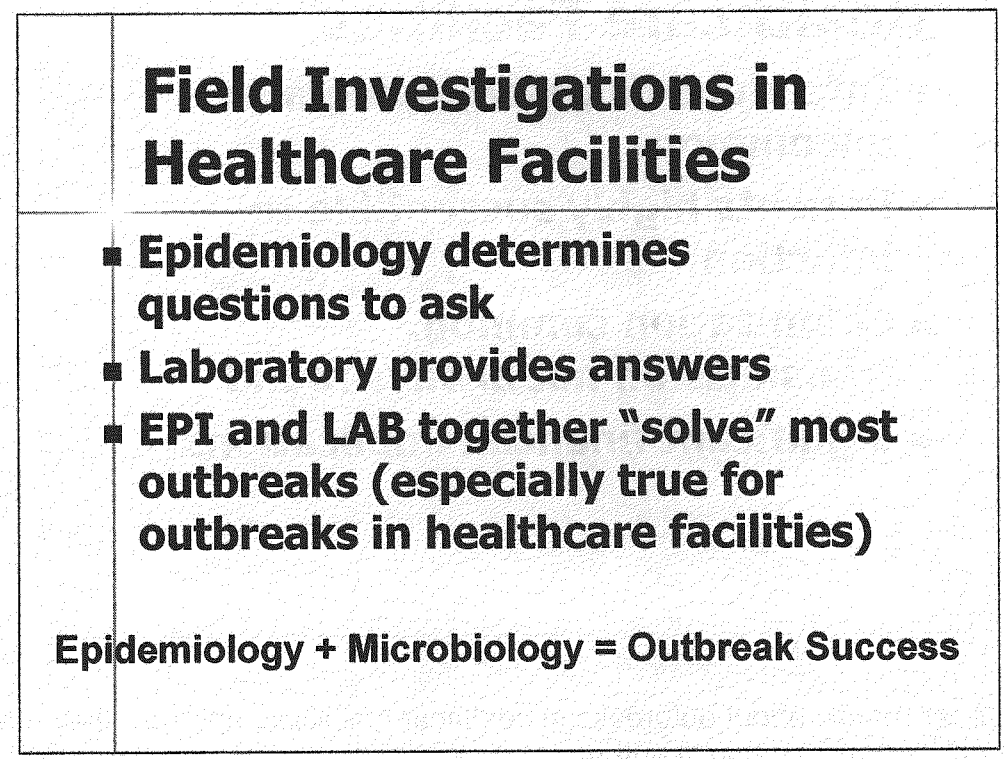
I'd like to talk briefly about outbreaks in healthcare facilities, and how they may differ from typical community outbreaks.

First, hospital-acquired, or nosocomial, infections are commonly found in the hospital, and may be seen in over 5% of hospitalized patients in the US. The most common type of nosocomial infection is a urinary tract infection, but pneumonia is also common. However, these infections seldom become epidemics caused by a particular bacterial strain.

One reason these infections are frequently seems obvious-patients in the hospital are sick. Intubation, central venous catheters, and Foley urinary catheters all render patients susceptible to hospital-acquired infections.

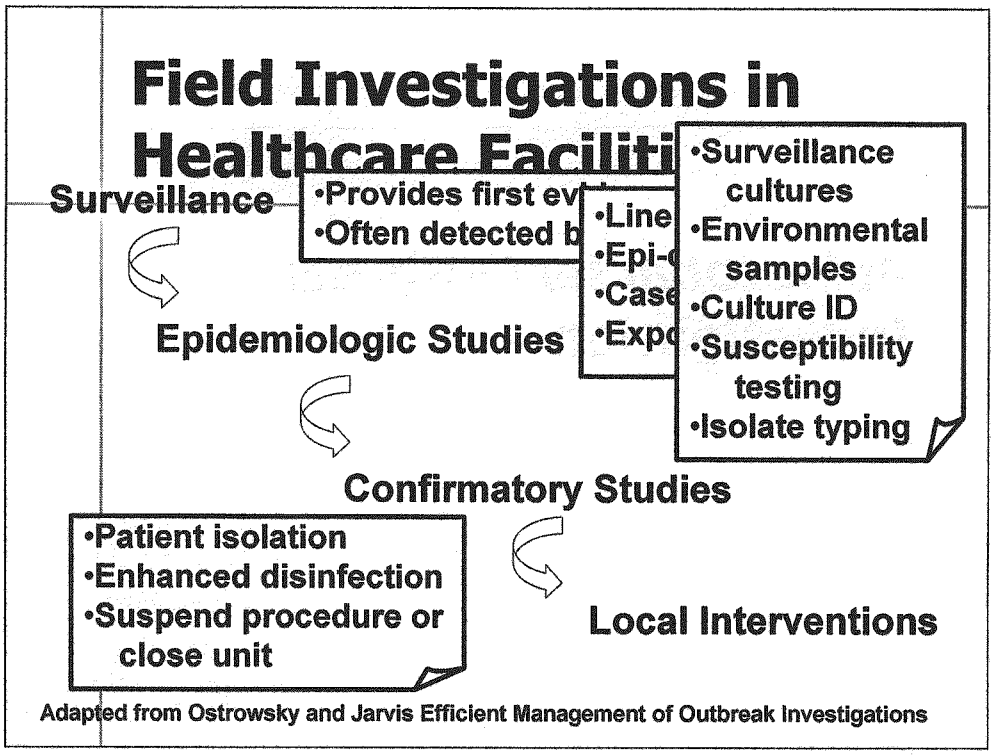
Identification of an organism causing infection may be difficult due to patient colonization with a particular organism. For example, Acinetobacter may be present on the skin or in the sputum of a patient, but may not necessarily be making that patient ill and therefore not found if cultures aren't performed. Because organisms can be present on the patient without causing disease, they might not be identified and therefore could be more easily spread if routine barrier precautions are not used.

A fourth issue in healthcare facility investigations is that these investigations can have significant financial implications. Control of hospital outbreaks may necessitate shutting down units and cohorting patients, which can be expensive to the hospital. The outbreak and investigation may also have legal implications.



In this type of investigation, the laboratory plays a significant role both in outbreak detection and in determining how an organism is spread. Often, the epi component of an investigation will determine the appropriate questions to ask, and the laboratory component will provide the answers.

And while this is true for most field investigations in general, it's almost invariably the case for hospital outbreaks. In the Acinetobacter outbreak, for example, the laboratory identified several isolates or strains causing disease. Knowledge of which pt had which strain enabled us to get a better idea of how the organism was being spread.



A hospital outbreak usually begins when ongoing surveillance signals a clusters of unusual infections.

ADVANCE

This provides the first evidence of an outbreak, and is often picked up by the microbiology lab.

ADVANCE

Epidemiologist in the field then help define the outbreak by providing a line-list of cases, an epi-curve which shows the distribution of cases over time, and perhaps results of a case-control study, which can give clues to exposures that are related to the disease in question.

ADVANCE

But it usually work done in the laboratory that confirms the suspicions raised by epidemiology. This may involve:

collection of surveillance cultures to see if the outbreak is ongoing,

collection and identification of environmental samples and clinical isolates,

susceptibility testing of organisms and molecular typing to see if they are related.

ADVANCE

Many hospital outbreaks end once the organism and its transmission dynamics have been determined. This usually results in local interventions such as isolation of patients, a change in disinfection protocol, or even suspension of an implicated procedure or closure of a unit until new cases cease to arise.

Acinetobacter Outbreak Investigation

Before we begin the investigation, we must prepare for field work. The preparation requires that we learn about the organism involved in the outbreak. So prior to going to the hospital, I did some reading about Acinetobacter. This is what I found.

Acinetobacter spp. Background

- Gram-negative bacillus
- Prior healthcare-associated outbreaks
- Traditionally associated with ICUs
- Increasing cause of serious illness

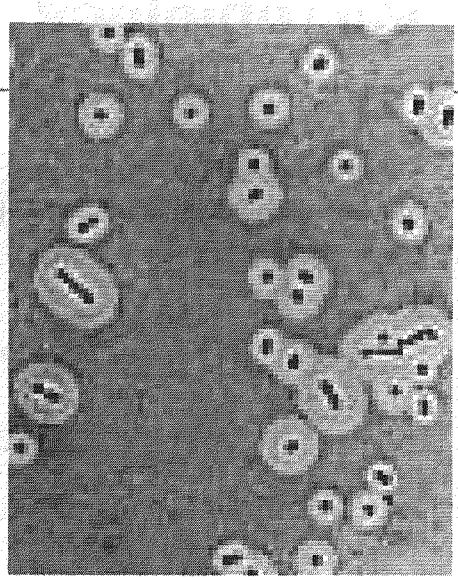


Image courtesy of Acinetobacter.com

Acinetobacter species are Gram-negative bacilli that are ubiquitous in the environment and are increasingly implicated in outbreaks of healthcare-associated disease.

Acinetobacter species are emerging as an important cause of serious illness in hospitals among susceptible hosts.

Microbiology

- **Ubiquitous:**
  - **Widely distributed in nature (soil, water, food, sewage) & the hospital environment**
- **Survive on moist & dry surfaces**
- **32 species**
  - **>2/3 of *Acinetobacter* infections are due to *A. baumannii***
- **Highly antibiotic resistant**

One of the things that makes this organism so problematic is its widespread presence in the environment and its ability to survive in the hospital environment. Acinetobacter has been cultured from dry surfaces in a patient room more than 9 days after an infected patient was discharged from the room.

Most of the Acinetobacter infections are due to the Acinetobacter baumannii.In addition, it readily acquires antibiotic resistance, even in the same patient.

Major infections due to *Acinetobacter*

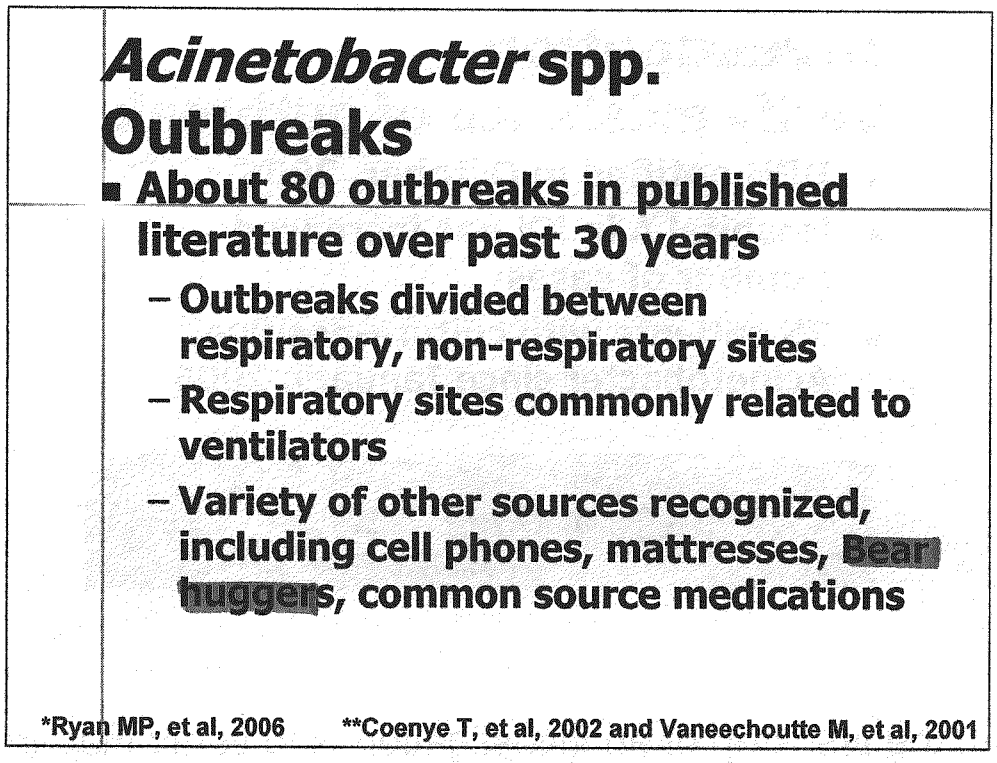
- Ventilator-associated pneumonia
- Urinary tract
- Bloodstream infection
- Skin/wound infections
- Endocarditis
- Peritonitis

Acinetobacter most commonly causes pneumonia, particularly ventilator-associated pneumonia. However, it has also been cultured from blood, urine, and wounds. It may less frequently cause meningitis, peritonitis, or endocarditis.

Acinetobacter Ventilator-Associated Pneumonia

- ***Acinetobacter*** **accounts for 5-25% of all cases of VAP**
- **Risk factors:**
  - **Advanced age**
  - **Surgery**
  - **Use of antimicrobial agents**
  - **Invasive devices**
  - **Prolonged ICU stay**

Some of the factors associated with previous outbreaks of Acinetobacter-associated pneumonia include one or multiple surgeries, patient requirement for multiple antibiotics, the use of devices such as central venous lines or arterial lines, and a long stay in the intensive care unit, such as with a critically ill trauma patient.



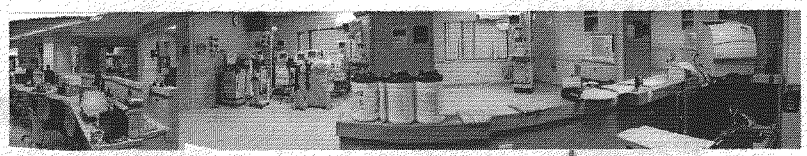
Because Acinetobacter is such a hardy organism, it was spread by a variety of means in previous outbreaks reviewed in the literature. Whether a common source is found may vary depending on whether the site of infection is respiratory or non-respiratory. Respiratory infections, obviously, are commonly associated with ventilators. Bear huggers used to warm patients after surgery, cellular phones used by caregivers, patient mattresses, and curtains have all been implicated in past outbreaks.

So, there is a lot of groundwork that can be put in learning about the organism. We also spent time learning about the hospital and spoke with CDC experts in hospital infections about the best way to go about investigating the outbreak.

Acinetobacter Outbreak Investigation

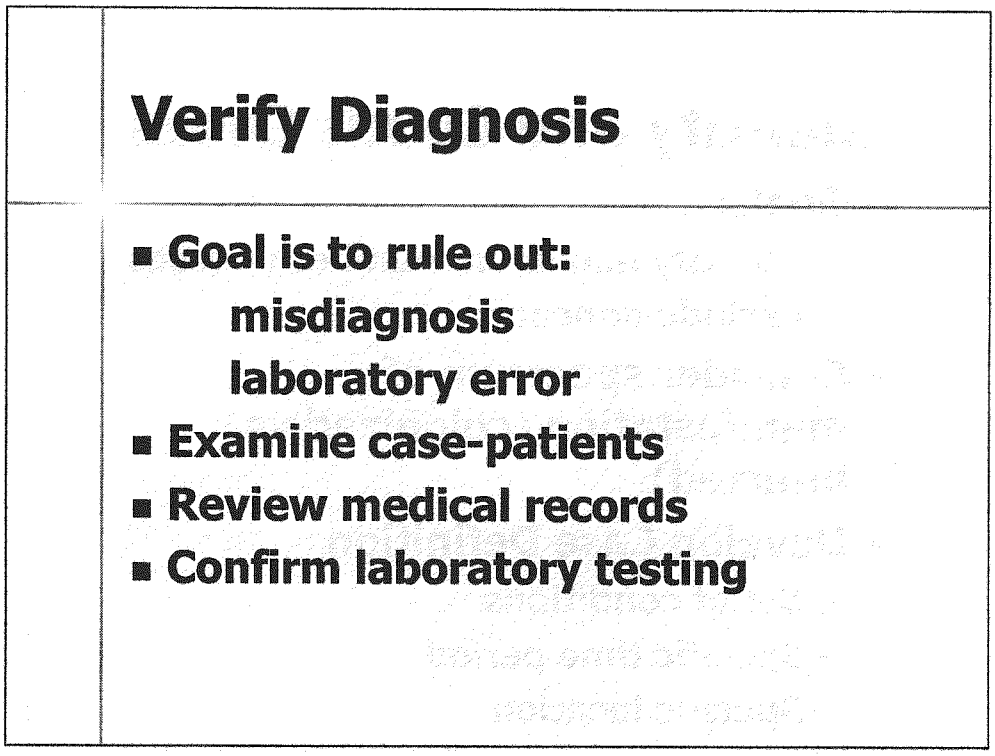
Verify existence of outbreak

- DPH notified in October, 2006
- Hospital A in KY has increased number of cases
- 75 patients with culture-positive Acinetobacter since January, 2006



Again, the first step of an investigation is to verify that an epidemic exists. Right at the start of this investigation, we've already done 2 of the 10 field investigation steps. We know (discounting for the moment the possibility of a pseudo-outbreak), that there *is* an outbreak in this hospital since they previously have had only 1-2 cases per month, but currently are reporting about 10-15 cases a month.

ADVANCE



We also actually have a good idea of the diagnosis thanks to the microbiology lab at Hospital A, which has identified an Acinetobacter species as the culprit. Although in this case the hospital and lab had established the diagnosis before we were contacted, that may not always be the case in a field investigation. Perhaps, for example, a group of healthcare workers have recently attended continuing education on MRSA. Their increased awareness might lead to greater number of diagnoses being made rather than what is truly an increased number of cases. Another possibility which might falsely lead us to the conclusion that an outbreak is occurring is that the lab has developed a test that is more sensitive than a previous test used for diagnosis was. In this case, we confirmed a true increase in the number of culture-positive patients with Acinetobacter.

Identify and Count Cases

- **Goals:**
  - **Identify maximum number of cases**
  - **Exclude noncases**
- **Consider spectrum of manifestation (colonized vs infected)**
- **Develop Case Definition**
  - **Set of conditions**
  - **Specific time period**
  - **Specific location**

The next step is to define what constitutes a case of disease, and to determine how many cases we have. We defined a case as a person admitted to Hospital A who developed a culture positive for Acinetobacter baumannii between April 1, 2006, and October 31, 2006. We also initially reviewed charts of patients with positive cultures found on active surveillance. However, ultimately we decided to focus on patients found on cultures performed to screen for disease. Therefore, we revised the case definition in order to increase our specificity.

Identify and count cases

- Conduct systematic search
- Use multiple sources
- Construct a line list

Once the case definition has been established, we then may begin to count our cases. In the case of our outbreak, the micro lab did work with the ICPs to identify an increased number of cases.

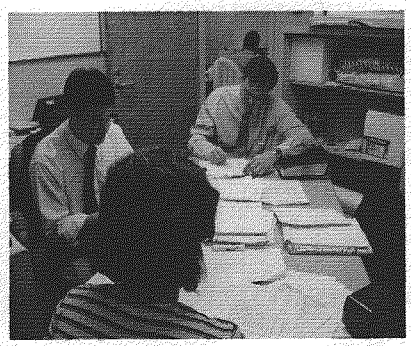
Cases may also be identified by reviewing medical charts or computer records, or by examining the ICP's surveillance system. We actually used several sources to find the information we needed on our cases. I'm sure a lot of you have reviewed charts or medical records in the past. Occasionally the information can be organized in a confusing manner, so we often verified the chart information with what was in the computer.

Once this data has been obtained, a line listing should be constructed in order to track the cases. The line listing of all cases identified enables the team to compare cases for possible commonalities. It also organizes information in a manner so that large amounts of data can be tracked in a small space. Again, the ICPS had done this work for us!

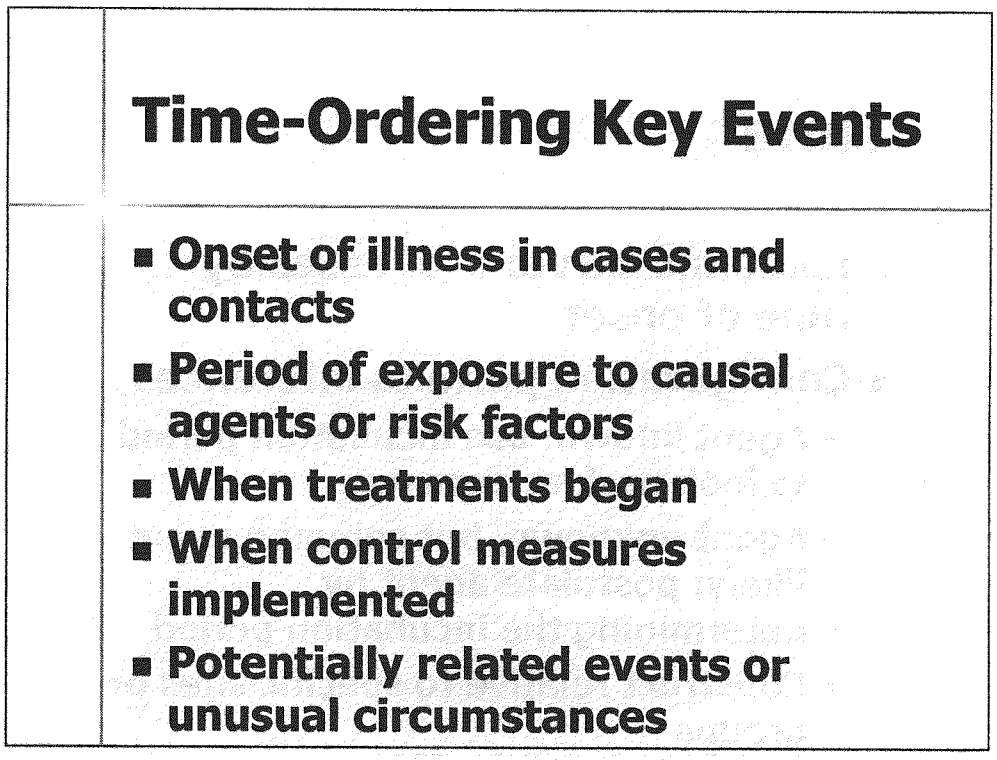
This picture illustrates the first step we took in investigating this outbreak. We performed a pretty extensive chart review on each of our cases. We used a 6 page abstraction form to make notes on the cases, including antibiotics they'd taken, surgeries they'd had, and admission to different ICUs. A lesson I have learned from this chart review is to try to use a shorter abstraction form, and to give thought to how the data on the form will be analyzed when we are creating the form.

Orient Data

- Person
- Place
- Time

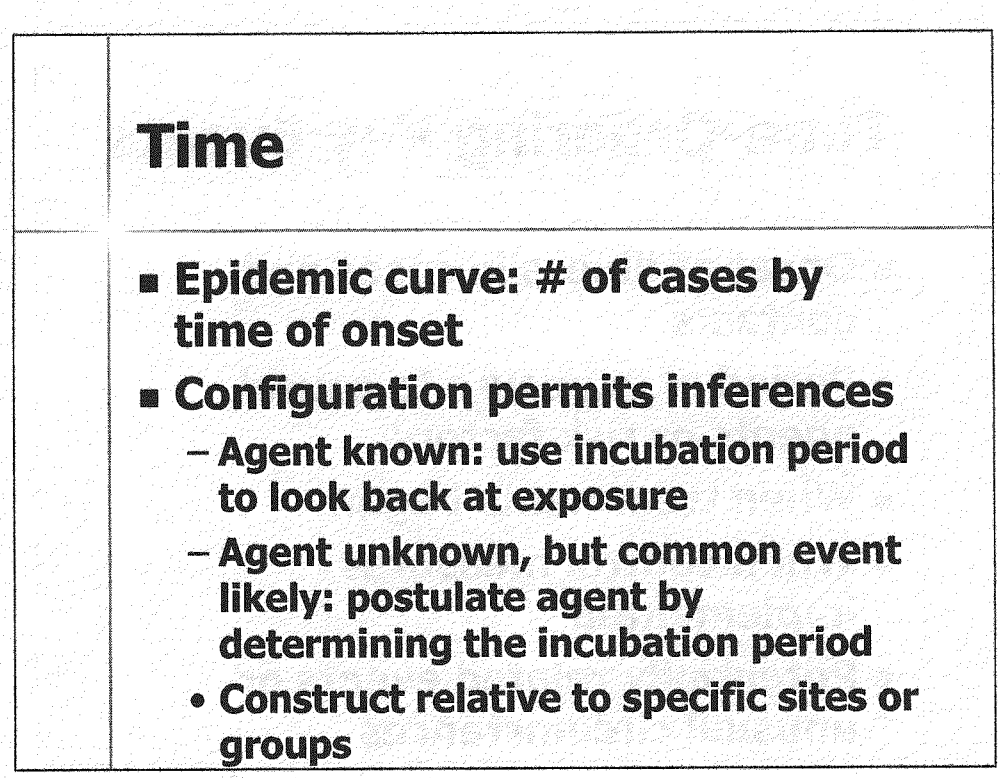


Although there are factors in the person-place-time orientation that differ between a hospital-acquired and community outbreak, the orientation of data in this fashion helps us to organize our thought process for the investigation. The questions we want to ask are those that any epidemiologist would use, namely, "who is affected, when were they affected, where were they affected, and ultimately how and why?" Again, the chart review we performed helped us answer some of these questions.



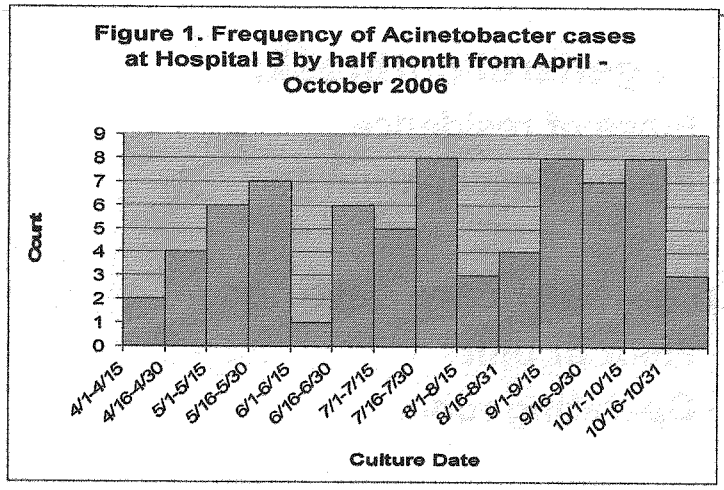
There are several questions we needed to ask when considering the role time plays in this epidemic. First, we want to know when people became ill.

Another factor which is important is time period of case exposure. We must also consider when treatments and control measures began, as these can both impact the history of the epidemic. Finally, we should consider other circumstances which might be related to an epidemic. For example, if we were investigating an outbreak of cholera, perhaps a breakdown in a sewage treatment system played a role in infections.



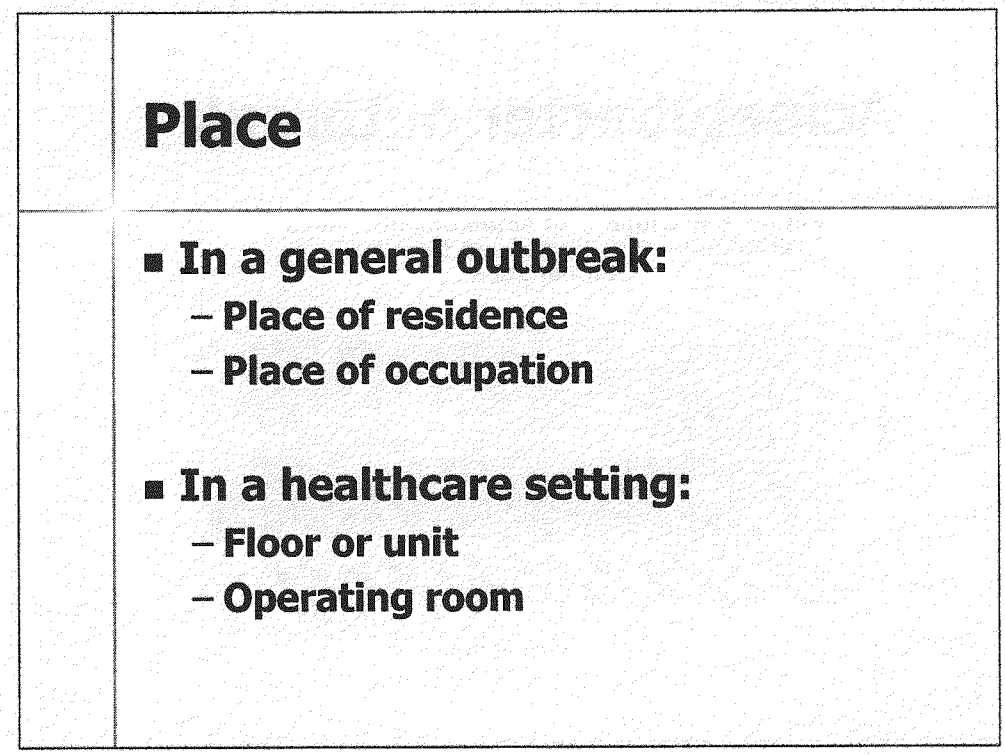
An epidemic curve is usually constructed after case identification. The configuration of the curve may be used to determine method of spread of a particular disease, the agent causing a disease, and whether or not an agent is being secondarily spread. Looking at the epi curve in this case allows us to focus on possible factors leading to increased transmission, such as a change in the way equipment is processed, a change in staffing, or a possible new bacterial strain.

Acinetobacter outbreak



This is the epi curve for our outbreak. Usually when we do an epi curve we like to show the period of time prior to the beginning of the outbreak, and the period after the outbreak ended if available. So I'm sure this curve isn't as well done as the ones you constructed this afternoon. However, I'll use it to illustrate a couple of points related to this outbreak.

This epidemic curve does not clearly demonstrate a point source of infection, in that cases do not show a high single peak at initiation of the outbreak. It does show multiple peaks, indicating an ongoing infection with potential spread among patients in the hospital.

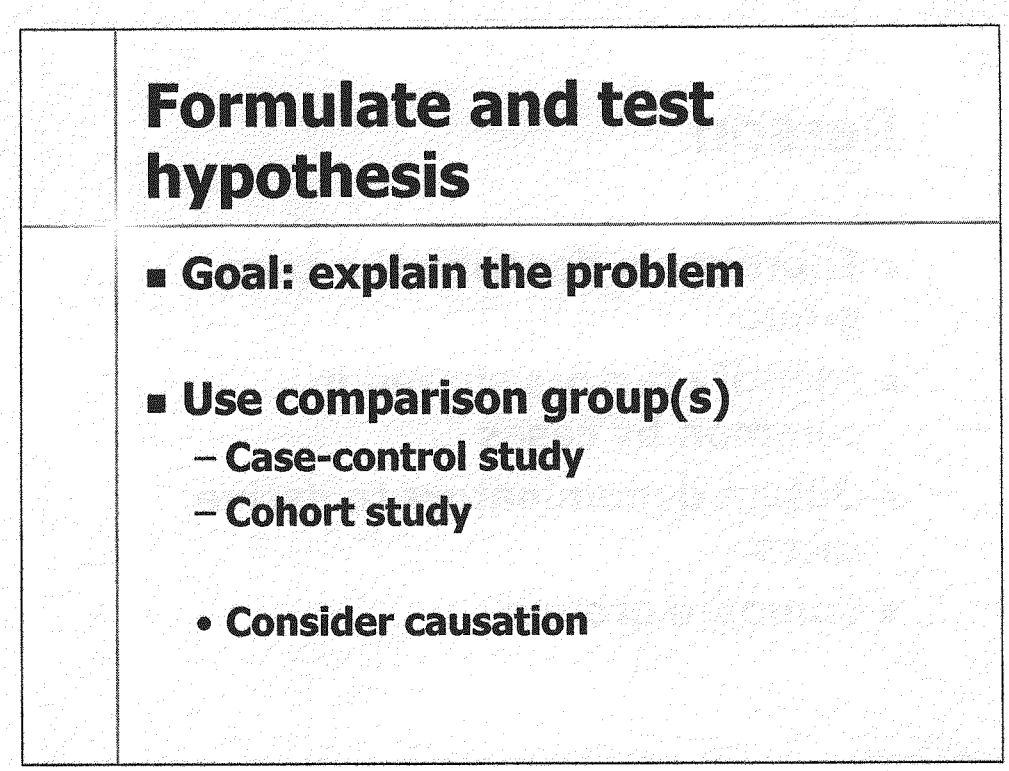


In other field investigations such as a foodborne outbreak, we orient cases by place to analyze risk at the state, local, or block level. Of course, the block where someone resides isn't relevant in a healthcare setting. There we consider the hospital location where cases are identified. Perhaps only a particular ward or type of ward, such as a surgical ward, has seen infections. These factors can all provide clues to the etiology of the outbreak. In this outbreak, we identified case-patients from several locations within the hospital rather than a single ward. However, we did notice an association between ICU admission and positive Acinetobacter culture.

Person

- Thoroughly describe the case group
- Identify factors shared in common by cases
- Obtain denominators to derive rates
- Compare groups

In other outbreak types we often use age, race, religion, occupation, and socioeconomic status in order to determine risk factors for illness. In a healthcare setting we more commonly wish to determine age, underlying disease, and invasive devices. In the acinetobacter outbreak, we looked at age, sex, admitting location, and past medical history of patients diagnosed. We also evaluated our case patients for need for invasive devices such as Foley catheters, arterial and venous lines, and intubation.



The next step in an outbreak investigation is to formulate and test hypotheses as to the method of disease transmission. We therefore use the information obtained by examining cases in terms of person, place, and time in order to develop a hypothesis. For example, if we determined that only intubated patients on a particular ward were developing nosocomial pneumonia, we might want to further evaluate intubation procedures, ventilators, and respiratory therapists that work on the ward in question.

We formulated our hypothesis based on previous work by the ICPs at the hospital and by evaluating data we collected there. We also used room observations to come up with ideas as to how the infection was spread. We went to wards and tried to remain inconspicuous while observing behavior in isolation rooms. This was also valuable for hypothesis generation.

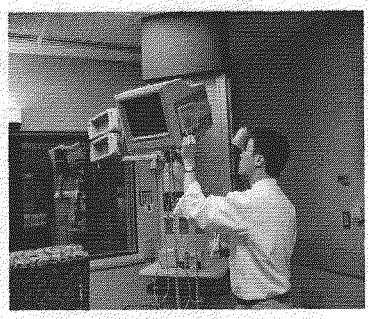
Compare Hypothesis with established facts

- **Environmental/staff cultures may be needed**
  - **Performed to aid in the investigation once theories are generated**
  - **Less valuable in generating hypotheses**

We are continuing to analyze our data, but so far our analysis is consistent with previous work done on Acinetobacter outbreaks. We have found that cases more commonly have a history of trauma, ventilation, and ICU than do controls. We plan to continue environmental sampling and to work with environmental staff and hospital staff to control the outbreak.

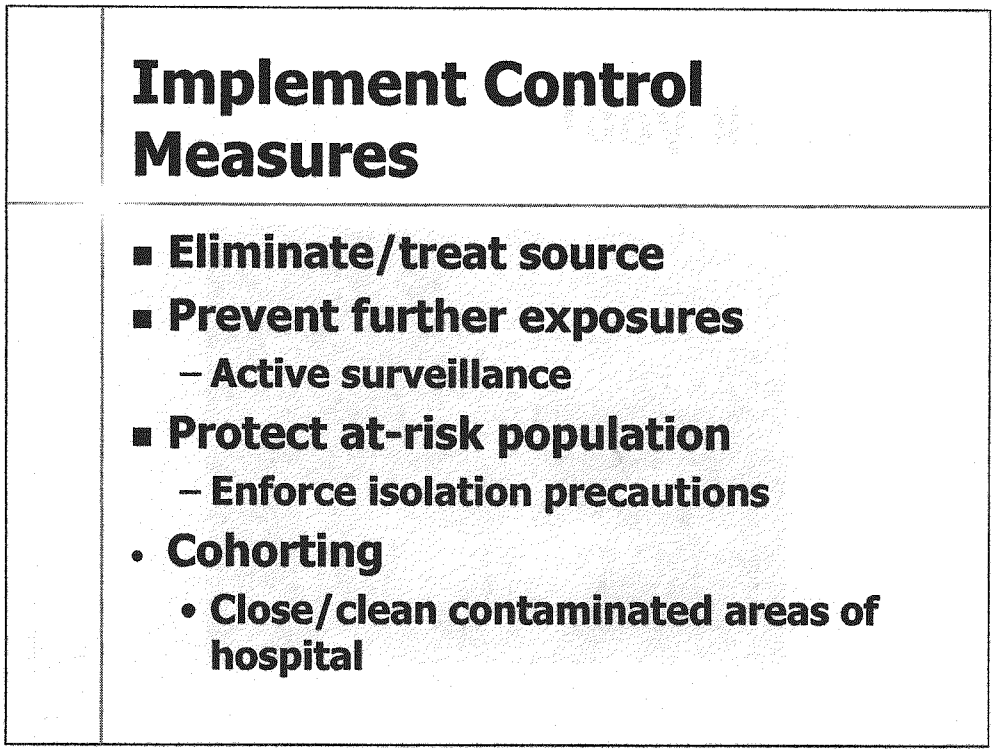
Plan More Systematic Study

- Control measures
- Continued data analysis



In the future, we plan to continue analysis of the data in our case-control study. We plan to use the data to perform environmental testing of areas which have been implicated by our analysis. We also are evaluating cleaning of high-touch areas by environmental services in the hospital.

Here's a picture of one of us doing environmental sampling to determine the level of contamination in a particular ICU. Unfortunately, it is often challenging to get these environmental samples to grow, so determining the level of contamination can be difficult.



Although the control methods are listed as the final step, they are often one of the first aspects of the investigation addressed by the field epi team. In a hospital outbreak, for example, while you are working on identifying risk factors, you may also want to reinforce isolation precautions. You may also cohort the patients, or group them into a single area so that spread of infection to other patients is less likely. Active surveillance is also used to identify colonized patients so that they may be placed in isolation.

Thank you!

Thanks for your attention! I'll be happy to answer any questions.

Dr. Suzanne Beavers
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February 16, 2009

TB Notes Newsletter

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No. 2, 2008

Personnel Notes

Suzanne Beavers, MD, will be the new staff epidemiologist for the Tuberculosis Epidemiologic Studies Consortium in the Surveillance, Epidemiology, and Outbreak Investigations Branch (SEOIB), starting July 1, 2008. She was born in Athens, Georgia, but spent most of her childhood in Punta Gorda, Florida. She graduated with high honors from the University of Florida with a degree in political science, and also obtained her MD degree from the University of Florida. She subsequently attended the Medical Center of Delaware for her internship and residency in emergency medicine. After practicing emergency medicine for several years, Suzanne became interested in a career in public health and epidemiology. She applied to the Epidemic Intelligence Service, was accepted into the Class of 2006, and served as Kentucky's EIS Officer from 2006 to 2008. As Kentucky's EIS Officer, she completed projects in infectious disease epidemiology as well as injury and maternal and child epidemiology. She looks forward to the opportunity to focus on tuberculosis epidemiology. We welcome Dr. Beavers to DTBE.

Deborah Bedell has accepted the Public Health Advisor (PHA) position in Tallahassee, Florida. She is returning to CDC after several years with the Alabama Sexually Transmitted Disease (STD) program. Deborah received a bachelor's degree in Human Services from Southern Illinois University 1979. She began her career as a case manager with the Alabama STD program, where she worked from 1982 to 1989. In 1989, she became a federal employee, joining CDC as a PHA in the STD program. She subsequently worked as a supervisor in Alabama; Baltimore, Maryland; Fulton County, Georgia; and Memphis, Tennessee. While in these assignments, she held various positions including outreach activities coordinator, front line supervisor, and manager. In 2003, Deborah left CDC and returned to the Alabama STD program. She earned a masters degree in Health Care Management from the University of Phoenix, Columbus, Georgia, in May 2006. FSEB welcomes Deborah back to the CDC fold as she begins this new phase in her public health career. She began her new job on May 27, 2008.

B

A1168
October 20, 2009
9:00 AM - 11:00 AM
Room Area A
Don't Forget To Change the Bair Hugger Filter
** Mark P. Gjolaj, M.D., Scott Ahlbrand, M.D., Imad M. Yamout, M.D., Donald Armstrong, John G. Brock-Utne, M.D., Ph.D.
Anesthesia, Stanford University Medical School, Stanford, California

Introduction

Forced air patient warming system such as Bair Hugger (BH) Augustine Medical Inc. Eden Prairie, MN, USA is a clinically effective patient warming device. However a potential disadvantage is that the BH may blow contaminated air.

Material and Methods

Under sterile conditions, cotton swabs were taken from the distal end of the BH tubing and the filter of the BH housed in each OR. All swabs were inoculated onto a Petri dish. Petri dishes were also exposed to ambient air from 29 OR's. The study was done at the time when the BH filters were recommended to be changed [after 6 months or more than 500 hours of usage]. The old filters were discarded and replaced. Three months later the study above was repeated.

Results

In the initial study we found that 8 out of 29 OR's to have had pathological growth. The distal ends of the Bair Huggers were positive for growth in 12 out of 29. Three Bair Hugger filters were positive. Three months later a repeat of the 8 positive OR's, 12 distal ends and the three Bair Huggers showed no growth.

Conclusion

The importance of changing the Bair Hugger filters is confirmed by the study. However the optimum timing as to when the filters should be changed is not clear. More studies are obviously needed. As an added safety feature, it has been recommended that an additional microbial filter be fitted to the distal end of the BH hose (1). The recommendation as to when this filter should be changed is unknown.

Reference

1. Avidan MS, Jones N, Khoosal M, Lundgren C, Morrell DF

Convection warmers – not just hot air. Anaesthesia 52. 1073-1076. 1997.

Elsevier Editorial System(tm) for American Journal of Infection Control
Manuscript Draft

Manuscript Number: AJIC-D-10-00049R2

Title: Forced Air Warming Blowers - An Evaluation Of Filtration Adequacy And Airborne Contamination Emissions In The Operating Room

Article Type: Original Research Article

Keywords: surgical site infection, forced air warming, laminar air flow, operating room environmental contamination

Corresponding Author: Professor David John Leaper, MD ChM FRCS FACS

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Abstract: Introduction: Forced air warming is widely used to prevent hypothermia during surgical procedures. The airflow from these blowers is often vented near the operative site and ought to be free of contaminants to minimize the risk of surgical site infection. Popular forced air warming blowers contain a 0.2 µm rated intake filter to lessen these risks. However, there is little evidence that the efficiency of the intake filter is adequate to prevent airborne contamination emissions or protect the internal air path from microbial contamination buildup.
Methods: Five new intake filters were obtained direct from the manufacturer (Arizant Healthcare, MN, Bair Hugger 505, model 200708D) and an additional five filters were removed from forced air warming devices (model 200708C) currently in hospital use. The retention efficiency of these filters was assessed using a monodisperse sodium chloride aerosol. In the same hospitals, internal air path surface swabs and hose outlet particle counting were performed on fifty-two forced air warming devices (all had the model 200708C filter) to assess internal microbial build-up and airborne contamination emissions.
Results: Intake filter retention efficiencies were found to be 93.8% and 61.3% at 0.2µm for the 200708C and 200708D filter models, respectively. The 200708D filters obtained direct from the manufacturer were constructed of a thinner filtration media than the 200708C filters in current hospital use, suggesting that the observed differences in retention efficiency were due to design changes. 58% of forced air warming blowers were found to be internally generating and emitting airborne contaminants, with micro-organisms detected on the internal air path surfaces of 92.3% of these blowers. Isolates of Staphylococcus aureus, coagulase negative Staphylococcus and meticillin resistant Staphylococcus aureus were detected in 13.5%, 3.9%, and 1.9% of forced air warming blowers, respectively.
Conclusion: The design of popular forced air warming devices having the 200708C filter was found to be inadequate for preventing the internal build-up and emission of microbial contaminants into the operating room. Sub-standard intake filtration allowed airborne contaminants (both viable and non-viable) to penetrate the intake filter and reversibly attach to the internal surfaces within the forced air warming blowers. The re-introduction of these contaminants into the forced air warming blower airstream was detected in this study, a process that may contribute to the risks of cross-infection.

Given the deficiencies identified with the 200708C intake filter, it is concerning to see a "newer" filter (model 200708D) being introduced having a substantially lower retention efficiency.

*Title Page (with author details)

Forced Air Warming Blowers – An Evaluation Of Filtration Adequacy And Airborne Contamination Emissions In The Operating Room

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Disclosure Statement

We will be sending via mail to editor with signatures.

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Key words: surgical site infection, forced air warming, laminar air flow, operating room environmental contamination

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introduction of these contaminants into the forced air warming blower airstream was detected in this study, a process that may contribute to the risks of cross-infection. Given the deficiencies identified with the 200708C intake filter, it is concerning to see a "newer" filter (model 200708D) being introduced having a substantially lower retention efficiency.

Introduction

Forced-air warming (FAW) has been widely adopted in clinical practice to prevent inadvertent hypothermia. This is based upon the well established benefits of normothermia during operative procedures, benefits that include reduced operative blood loss, improved wound healing, reduced duration of hospital stay, improved survival, and reduced surgical site infection (SSI) rates.[1-6] However, the airflow from these FAW devices is often vented into the sterile field adjacent to the operative site and should, ideally, be free of contaminants to minimize the risks of SSI. Popular FAW devices, which are currently in widespread use, contain a "0.2µm" rated intake filter to lessen these risks.[7] However, we are not aware of any published evidence showing that the efficiency of the intake filter is adequate to prevent airborne contamination emissions or to protect the internal air path from a buildup of microbial contamination.

Airborne contamination consists of all particulate matter suspended in the operating room (OR) air. Common forms include microbial-laden dust, fibers from theatre clothing and operative drapes, desquamated skin, and respiratory droplets.[8-10] These contaminants are mobilized by air currents, and have been shown to settle out of the air onto the operative site, contributing to the risk of a SSI through at least two likely mechanisms: pathogenic contaminants can be the direct cause of an SSI; and non-pathogenic contaminants can lead to an SSI through the formation of a nidus for microbial attachment and growth.[11] The level of airborne contamination in the operative site does not need to be large as the risk of a superficial or deep SSI increases exponentially when a foreign body, such as a hip or knee prosthesis, is present.[12,13]

To limit the associated risks of airborne contamination, OR ventilation is designed to meet minimum filtration efficiency standards of 90%.[14] For many contamination-sensitive operations, particularly in the orthopedic and cardiovascular fields, ORs routinely employ high efficiency particulate air (HEPA) ventilation for added protection. HEPA filtration, by definition, meets minimum filtration efficiency standards of 99.97% at 0.3µm. As mentioned previously, most FAW devices employ a "0.2"µm rated intake

filter to prevent the emission of airborne contamination. However, the micron rating of a filter conveys no information about the quality of the filter. The key parameter is the "filtration efficiency" or "retention efficiency" at the stated micron rating. The manufacturers of FAW blowers do not disclose the filtration efficiency of their intake filters.[7] Therefore, it is difficult to evaluate the adequacy of FAW intake filters for preventing the mobilization of airborne contaminants in the OR. Further, recent research by the current authors has identified a number of FAW devices that were emitting excessive levels of airborne contamination in an OR environment.[15] The cause of these emissions was postulated to be related to airborne contaminants penetrating the intake filter over a prolonged period.

In terms of preventing a buildup of internal microbial contamination, the FAW blower intake filter has been identified as deficient by a number of researchers. Prior studies have routinely found microbial colonization.[16-18] inside the majority of sampled FAW blowers and one study repeatedly cultured microbes from the blower's airstream; the authors of this latter study recommended the placement of a distal hose end filter to lessen the risks of microbial emissions.[16] However, other studies assessing settle plate colonization levels have not detected any significant differences with the use of FAW in the OR.[19-21] The results of these studies are difficult to interpret given that only a small number of FAW blowers were sampled, and that they did not take into account that these FAW blowers may or may not have been internally contaminated based upon their hours of use and number of environmental exposures.

Because of the perceived infection risks, many ORs have been reluctant to use FAW to maintain normothermia[22]. Air-free alternatives to FAW have recently been developed; alternatives such as conductive mattresses and blankets that: 1) have been shown to be comparably effective in randomized clinical trials [23-29] and, 2) do not pose similar risks of airborne contamination. With the availability of these clinically validated alternatives, it is important to assess whether the design of FAW blowers is adequate for preventing airborne contamination emissions in the OR. Given the critical role of the intake filter for

preventing contamination emissions and buildup within FAW blowers, the rationale of the current study was focused on:

(i) Rating the retention efficiency of two popular types of pleated gas intake FAW filters using industry filtration challenge standards;

(ii) Assessing the performance of FAW filters in the environment of their use (the OR) by isolating the filters from the FAW devices and challenging them on a special test fixture;

(iii) Quantifying airborne contaminants in the effluent airstream that were generated downstream of the intake filter within the FAW blower; and

(iv) Culturing the internal FAW blower internal air path surfaces for any buildup of microbial contamination.

Methods

Sampling Procedures

FAW blowers, from hospitals in the vicinity of Minneapolis and St. Paul, MN, USA, were sampled after-hours in the operating room to quantify:

(i) The emission of airborne contamination from their distal air stream, which was recorded using a calibrated laser particle counter (Handilaz Mini, Particle Measuring Systems, Boulder, CO, USA). Particle counts were taken within the intake and distal hose end airstreams: for the intake sample, the probe was placed 2-5 cm from the intake filter; for the distal sample, the probe was placed 2-5 cm inside the distal hose end. Three 1-minute 0.1-ft^3 samples were taken at each location.

(ii) The performance of the intake filter in the OR environment, which was measured separately from the FAW blower using a portable test fixture that challenged the intake filter with ambient operating room air. The fixture consisted of a downstream vacuum (calibrated to draw 35 ft^3/min of ambient operating room air through the filter), a mounting plate, and an internal particle sampling pitot tube which was located downstream of the filter in the center of the air channel before the vacuum. With the intake filter affixed to the fixture and the vacuum running, particle counts of a 0.1 ft^3

sample volume were taken upstream and downstream of the intake filter: for the upstream sample, the probe was placed 2-5 cm from the exposed filter media surface; for the downstream sample, the probe was coupled to the sampling pitot tube using a 7 cm tubing extension. Three samples were taken at each location.

(iii) Microbial colonization of the internal air path surfaces, which were sampled using swabs moistened with Butterfield's buffer solution. Moistened swabs were rubbed against approximately a 10 cm^2 area for the following internal air path surfaces (**Fig 1**): (**A**) exposed plastic surfaces of structure supporting the motor directly downstream of the intake filter; (**B**) injection molded elbow connecting the proximal hose to the unit; and (**C**) injection molded proximal (unit-end) and (**D**) distal (out-put-end) hose fittings. Four control swabs, representing the swab set for a complete unit, were also taken simultaneously and sent to the microbiology laboratory in a blinded fashion with the active samples. The control swabs were taken by moistening the swab with Butterfield's buffer and placing the swab directly into its transport container.

Intake FAW blower filters were acquired for further testing from both the manufacturer in new condition (Arizant Healthcare, Eden Prairie, MN, USA) and used condition from FAW devices in ORs for quantification of:

(iv) Intake filter retention efficiency, which was measured by challenging the filters through a range of monodisperse particle sizes (0.025 to 0.5 µm). An industry standard filtration test fixture was employed that utilized a blower and high efficiency particulate air (HEPA) filtration to remove all ambient particulate from the challenge air. An atomizer (Quant Technologies LLC, Blaine, MN, USA) provided a polydisperse sodium chloride (NaCl) aerosol to an aerosol neutralizer (Model 3077, TSI, Inc, Shoreview, MN, USA), which utilized a krypton-85 radiation source to neutralize the particle charge distribution to Boltzmann equilibrium levels. An electronic classifier (Model 3080, TSI, Inc, Shoreview, MN, USA) then selected a portion of the polydisperse NaCl aerosol based upon its electronic mobility diameter, thereby producing a monodisperse NaCl aerosol. This monodisperse NaCl aerosol was injected into the challenge airstream.

Simultaneous measurements of upstream and downstream particle concentrations were made using two condensation particle counters (Models 3772 and 3782, TSI, Inc, Shoreview, MN, USA). An air velocity meter (Dwyer Instruments, Inc, Michigan City, IN, USA) was used to record the challenge airflow (ranged from 30 to 45 ft^3/min).

Assessments

Microbiological culturing and analysis were performed by PACE Analytical, Oakdale, MN, USA. Assessments of intake filter retention efficiency were performed by CT Associates Inc, Eden Prairie, MN, USA.

Filter retention efficiency was calculated as the fraction of particles captured by the filter over a 5 to 10 minute challenge period in [redacted]. Retention efficiencies were measured for each filter at six monodisperse particle challenge sizes: 0.025 µm, 0.05 µm, 0.1 µm, 0.2 µm, 0.3 µm, and 0.4 µm; some filters were challenged at a seventh particle size of 0.5 µm. Challenge concentrations varied from [redacted] particles/ft^3, depending on particle size. The most penetrating particle size (MPPS) is defined as the particle size at which the filter displayed a minimum retention efficiency.

Intake filter performance in the OR environment was assessed as the fraction of particles >0.3 µm captured by the intake filter when challenged by ambient operating room air on the [redacted]. A 6 minute challenge period was used for each filter, in which upstream and downstream measurements were sequentially performed. Reported values for "upstream" particles were calculated as the average particle concentration upstream of the intake filter. Similarly, reported values for "downstream" particles were calculated as the average particle concentration downstream of the filter.

Expected distal airstream particle emissions were calculated for each FAW blower by: (i) computing the average particle concentration >0.3 µm in the intake airstream, and (ii) multiplying the average intake airstream particle concentration by the fraction of particles >0.3 µm removed by the intake filter (as observed during intake filter

performance testing). Intake airstream particle concentrations were measured over a 3 minute sampling period.

Deviations from expected distal airstream particle emissions were calculated for each FAW blower by subtracting the expected distal airstream particle concentrations from the observed distal airstream particle concentrations >0.3 µm. Distal airstream particle concentrations were measured over a 3 minute sampling period. The deviation from expected distal airstream particle emission represents the quantity of particulate emission that was generated inside the FAW blower downstream of the intake filter.

Colony forming units (CFU) per swab were assessed by the following process: swabs were transported from the site in 5 ml of Butterfields's buffer on ice; the diluent and swab were vortexed in a transport container for 30 seconds; in duplicate, 1 mL of the sample was pipetted into a Petri dishes and 25ml of molten 45°C tryptic soy agar was added to form a non-selective growth medium; the dishes were incubated for 48 to 72 hours at 36.0 ±0.1°C; and finally, they were inspected for micro-organism growth and each individual colony was counted as a single CFU. Reported CFUs per swab represent the average colony counts recorded between the two Petri dishes multiplied by a conversion factor of five. Reported CFUs for the locations of distal hose, proximal hose, elbow, and motor stack are the CFUs reported for the single swab used at each location (Fig.). Combined CFUs per FAW blower are the sum of the CFUs reported at each of the four swabbing locations.

The presence of specific micro-organisms was assessed for each swab through enriching and incubating the remaining diluent (24 hours at 36.0 ±0.1°C), and then testing for: *Staphylococcus aureus* and coagulase negative *Staphylococcus* (CoNS), using mannitol salt agar; and meticillin resistant *Staphylococcus aureus* (MRSA), using CHROMagar™ (BD Inc., Franklin Lakes, NJ, USA). Other *Staphylococcus* species were not identified.

Statistical Analysis

FAW blowers having significant deviations from expected distal air stream particle emissions were identified using a variance weighted ANCOVA model having particle outflow concentration as the response. Predictors included: intake particle concentration as a covariate; and FAW blower serial number and treatment (filter isolated or filter on FAW blower) as fixed effects. Significant treatment differences were identified as those having *P* values less than 0.05 (2-tailed).

Pearson correlation coefficients were calculated to assess the linear correlation between FAW blower particulate emissions (generated downstream of the intake filter) and CFUs detected for each swabbing location (distal, proximal, elbow, motor stack, and combined). *P* values represent the 2-tailed probability that the Pearson correlation coefficient is equal to zero.

Results

52 FAW blowers (Bair Hugger, Model 505, Arizant Healthcare, Eden Prairie, MN) were sampled in their surgical environment of use (the ORs) from 11 hospitals; only OR dedicated FAW blowers were sampled. Sampling was conducted in 38 separate ORs where FAW blowers were sometimes moved to a common OR for sampling that shared the same central hospital ventilation as the other ORs. The distribution of ambient OR air quality provided by the ventilation system differed greatly by hospital ([redacted]) with ventilation quality ranging from 0 to 800,000 particles >0.3 µm per ft^3 centered on a median of 8,600 particles >0.3 µm per ft^3; upper and lower quartiles were 130,000 and 3,600 particles >0.3 µm per ft^3, respectively.

Intake Filter Retention Efficiency

The retention efficiencies for 200708C (n=5) and 200708D (n=5) filter models differed greatly, with mean reported retention efficiency values of 93.8% and 61.3% at the MPPS of 0.2µm, respectively ([redacted]). A visual inspection of both filter models revealed that the filtration media was thinner for the 200708D model than the 200708C model, a

difference that was particularly apparent when both filter models were held up to a light source.

Intake Filter Performance in the Surgical Environment

52 of the 200708C model intake filters were challenged with OR air and 47 of those intake filters appeared to have consistent efficiencies within the expected range of operation (Fig. 3); 5 intake filters sampled in "dirtier" environments appeared to have lowered filtration efficiencies. A linear no-intercept regression model was fitted to the data for the 47 intake filters having consistent performance and identified a filtration efficiency of 95% for particles >0.3 µm as the best fit.

FAW Blower Generated Particles

Distal hose end air stream particle emissions were well above what would be expected for the majority of FAW blowers (n=30) based upon reported intake filter performance. Deviations from expected distal particle emissions for each FAW blower- a quantity based upon measured intake filter performance and distal particle emissions for each individual unit- revealed that 58% of FAW blowers were generating significant levels of contamination >0.3µm in size. These FAW blowers were emitting up to 35,000 particles per ft^3 down-stream of the intake filter (Fig. 4). The magnitude of FAW blower particle generation was loosely correlated with ambient OR air particulate concentrations.

FAW Blower Air path Colonization

Air path swabs from FAW blowers revealed the presence of viable micro-organisms in 92% FAW blowers (Fig. 1), with the heaviest growth reported on the internal air path surfaces of the distal hose end (Fig. 5). Isolates of *Staphylococcus aureus*, coagulase negative *staphylococcus* (CoNS) and meticillin resistant *Staphylococcus aureus* (MRSA) were detected inside 13.5%, 3.9%, and 1.9% of FAW blowers, respectively. Pearson correlation coefficients indicated a lack of correlation between blower generated particles and internal levels of microbial colonization for the combined CFU measure (p=0.09) and all individual swab locations (distal, p=0.09; proximal, p=0.34; elbow, p=0.26; and motor, p=0.99). Microbes were detected on the non-specific growth medium for a small

proportion of control samples (9%); all micro-organism specific control samples were negative.

Discussion

The results of this study suggest that popular FAW devices, which were in current use, are of questionable design with regard to preventing airborne contamination emissions into the OR and, possibly the surgical field. Inadequate FAW blower intake filtration (93.8% for model 200708C and 61.3% for model 200708D) resulted in an internal buildup of microbial contamination within the majority of FAW blowers (92%) on inaccessible air path surfaces. The majority of FAW blowers (58%) were also found to be internally generating airborne contamination downstream of the protective intake filter. This may have been related to the release of built-up contaminants acquired during prior periods of use in environments having elevated levels of ambient airborne contaminants. This is the first study which has focused on assessing FAW blower intake filter performance and its relationship to FAW blower-generated airborne contamination.

We felt it was important to characterize the intake filter separate from the FAW blower because prior research identified elevated levels of contamination emission from a number of FAW blowers,[15] but the source of this contamination could not be conclusively identified as being downstream of the intake filter. By characterizing the performance of each FAW blower intake filter in its environment of use (the OR), the current study was able to determine expected particle emissions from FAW blowers and isolate emissions in excess of this expected value as being introduced downstream of the intake filter within the FAW blower. However, this study was limited in its ability to identify the exact composition of these emitted contaminants because we identified only select micro-organisms through swabbing and did not collect particulate samples for assessment through microscopy. Nevertheless, prior research, reported intake filter retention efficiencies, and swabbing results provide some general information of as to the source of such contaminants.

Earlier research, which studied the size distribution of airborne contaminants upstream and downstream of FAW blowers, concluded that air leaks on the intake side were an unlikely source of the contaminants.[15] This leaves the wear-and-tear of moving components or the release of built-up contaminants as the most probable causes. The disintegration of moving components is an unlikely source because the generation of contamination was not uniform for blowers having similar internal components. This trend of non-uniformity is apparent in [redacted] if one considers several relationships: first, FAW blowers having similar levels of intake particulate challenge typically belong to the same hospital; secondly, these FAW blowers within a single hospital generally come from the same manufacturing lot and, thus, have similar internal components; and finally, these groupings of similar lot blowers, based upon intake particulate challenge, would be expected to exhibit uniform trends of contamination generation. However, this correlation is not apparent in [redacted]. In contrast, the release of built-up contaminants appears to be a probable cause based upon reported FAW blower intake filter retention efficiencies.

All of the FAW blowers that were assessed in the OR from this sample population had the 200708C intake filter model, which had a reported retention efficiency of 93.8% when challenged by a specific size of particulate (0.2µm). Additionally, performance data suggests that most 200708C filters performed near or within specification in the OR when challenged with ambient air (95% at >0.3µm). Yet, this level of intake filtration implies that approximately 5 to 7% of ambient airborne contaminants pass through the intake filter and into the FAW blower. These airborne particles (viable and non-viable) are likely to reversibly attach to the FAW blower's internal plastic air path surfaces, particularly since plastic surfaces tend to develop an attractive static charge in the presence of a particulate laden airflow.[30]

As such, the nature of contaminant(s) contained in the FAW blower is likely to depend on both the past and current environments of use. The typical location for FAW blowers in the OR tends to be near the floor by the head of the operating table. Movements of the surgical staff and patient have been shown to generate large quantities of desquamated

skin cells, of which as many as 10% have been shown to carry viable micro-organisms.[31,32] Studies have shown these shed skin cells to have a wide particle size distribution extending well below 5µm due to flake fragmentation [33,34], thus, a large portion of these skin cells are small enough to become buoyant and follow the downward nature of the laminar air flow towards the FAW blower intake. The efficiency of the intake filter suggests that a large number of these potentially pathogen-carrying cells may penetrate the filter and build-up on the FAW blower's internal air path surfaces. This mechanism of airborne skin cell "seeding" is a probable explanation for the 92% internal colonization rate, which is further supported by the findings that approximately 15% of reported isolates were skin specific organisms, namely *Staphylococcus aureus* and coagulase negative *staphylococci* (CoNS). Additionally, FAW blowers are often moved between clean-air OR environments and the recovery room, a practice that may exacerbate the airborne contamination that these FAW blowers are exposed to. This relationship between environmental exposures and the degree of FAW blower contamination generation can be seen in Fig 4, where the degree of contamination generation appears to increase in ORs having higher ambient particulate levels.

The concept of "seeding" also presents the possibility of microbe growth and aerosolization from internal FAW blower surfaces. Deposited contaminants may act as the nutrient source necessary to sustain microbe growth. However, Pearson correlation coefficients demonstrated no conclusive relationships between detected CFUs and emitted contaminant levels, which suggest that a large portion of emitted contaminants were non-viable in nature. The results of this study warrant future research into this matter.

Nevertheless, the relevant clinical risks relate to the potential release of these airborne contaminants from FAW blowers in the vicinity of the surgical site. The findings of this study do not directly establish a link between FAW and increased SSI rates, but they do raise awareness to the potential risks associated with FAW use. Further, the results of this study and those of others [15-18] have demonstrated appreciable microbial contamination on the internal air path surfaces of FAW blowers, contamination

consisting of common pathogenic isolates (*Staphylococcus aureus*, CoNS, MRSA) that are typically involved in superficial and deep SSIs.[11] These isolates, as free-floating bacteria, are commonly found in ORs and range from 0.5 to 4μm in particle size,[35] a particle size that corresponds to the size distribution of FAW blower borne contamination detected in this study. In prosthetic surgery all of the identified organisms are associated with appreciable morbidity and mortality, and may lead to the need for revision or removal of an infected prosthetic joint.[36] Moreover, the potential for the mobilization and release of built-up pathogenic contaminants suggests that FAW blowers may elevate the risks of cross-contamination between operations. For example, in one study FAW blowers were implicated as the causative factor in an outbreak of *Acinetobacter baumannii*.[18]

The results of this study highlight three primary design inadequacies of FAW blowers that contribute to the buildup and release of contaminants. First, the inaccessible nature of the internal FAW blower air path surfaces prevent regular cleaning and decontamination. This is in contrast to guidelines from the European Union Medical Device Directives, US Food and Drug Administration, and Health Canada regarding reusable medical equipment that either require or recommend manufacturers to offer a means for decontamination.[37-39] Secondly, current FAW blower intake filtration measures are inadequate to prevent the buildup of micro-organisms on internal air path surfaces. Finally, the design of current FAW blowers does not include an outlet filter that could prevent the emission of contaminants into the OR. FAW device manufacturers should be encouraged to re-design FAW blowers such that: 1) internal surfaces are accessible for decontamination; and, 2) true HEPA filtration (>99.97% at 0.3μm) is offered as a protective measure at the intake and hose outlet. In the meanwhile, hospitals and care-providers may consider periodic sterilization procedures for reconnectable components of their FAW machines. Additionally, it is concerning to see the introduction of a "newer" filter (model 200708D) in popular FAW blower models having a decreased filtration efficiency (61.3%).

Conclusion

This study highlights the potential risks of intra-operative surgical site contamination when FAW devices are used in clean OR environments. These risks may be elevated for contamination sensitive operations, such as prosthetic elective surgery, that demand laminar-HEPA-airflow ORs. The need to avoid inadvertent hypothermia is now well-recognized [40] and is part of the mandatory checklist in the "Safe Surgery Saves Lives" campaign promoted by the World Health Organization.[41] This study suggests that it would be prudent to add HEPA filtration to the intake and outlet of FAW blowers to lessen the risks contamination emission and mobilization in the OR environment. Alternatively, air-free warming technologies, such as conductive fabric mattresses and blankets,[23-29] that are easy to decontaminate should be considered.

Figures

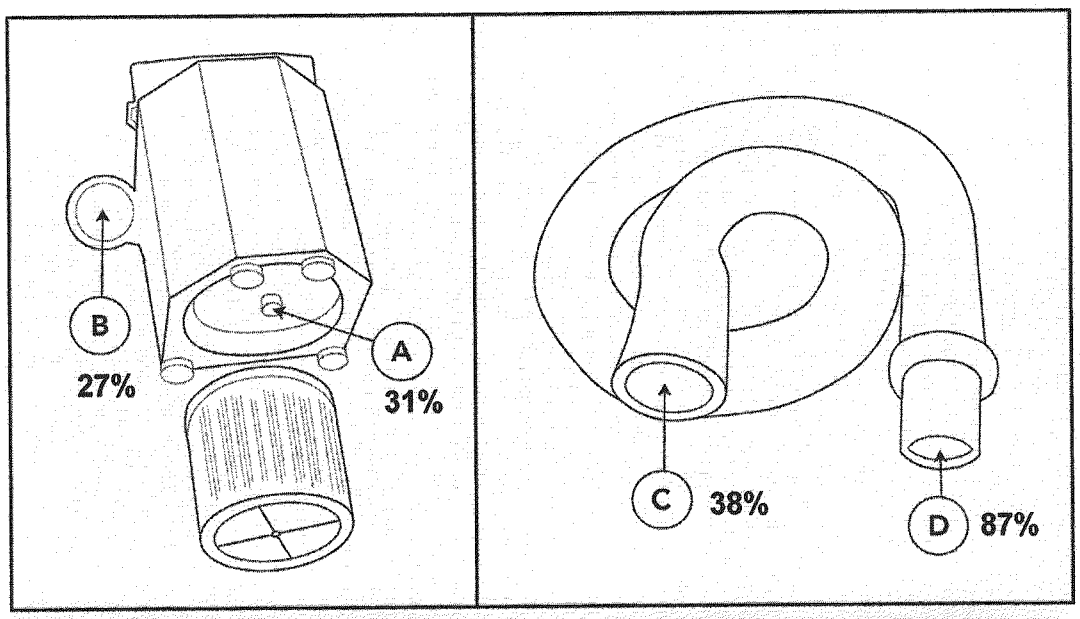

Figure 1: Detection rates for non-specific micro-organisms on FAW blower (n=52) internal air path surfaces by swabbing location: (A) motor stack; (B) elbow; (C) proximal hose ends and (D) distal hose ends

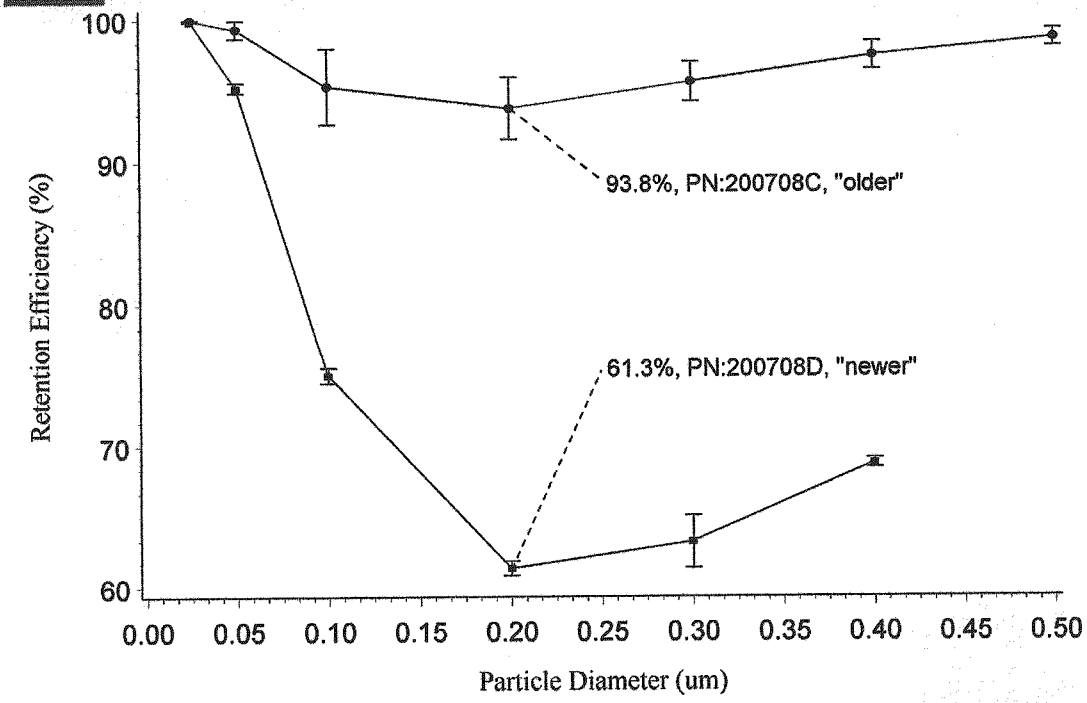

Figure 2: Mean retention efficiencies for intake filter models 200708C (n=5) and 200708D (n=5) with dispersion indices (±1 standard deviation). Efficiency rating at most penetrating particle size shown for each filter.

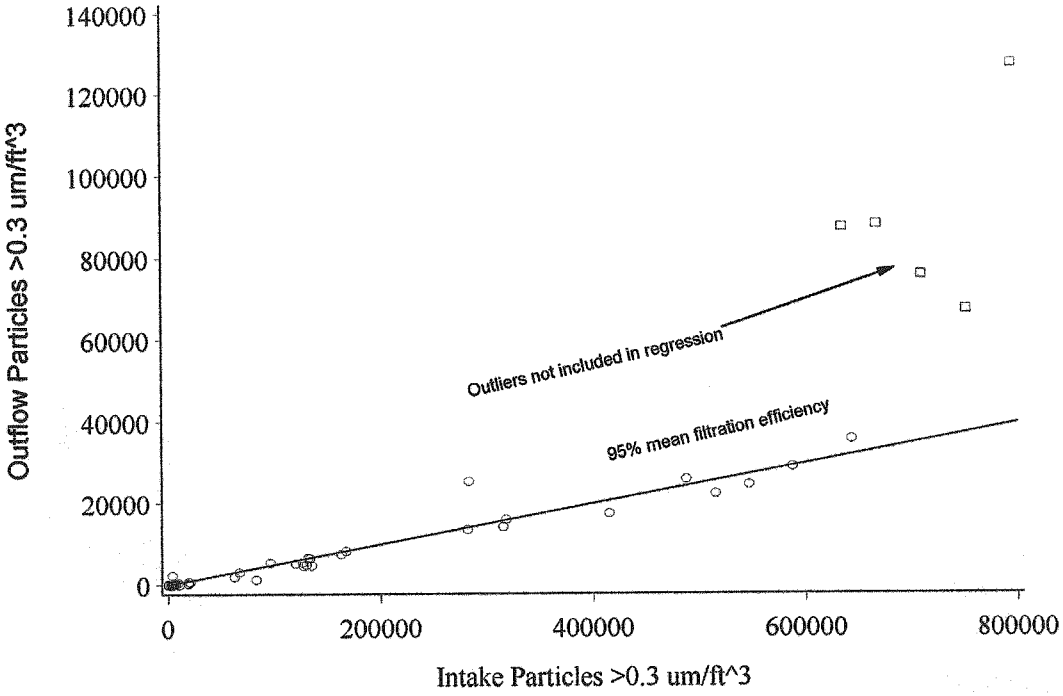

Figure 3: Intake filter performance in the surgical environment of use as assessed with the operating room challenge fixture (Fig 1). Individual intake filter performance values (n=52) are displayed along with a fitted no-intercept linear regression model.

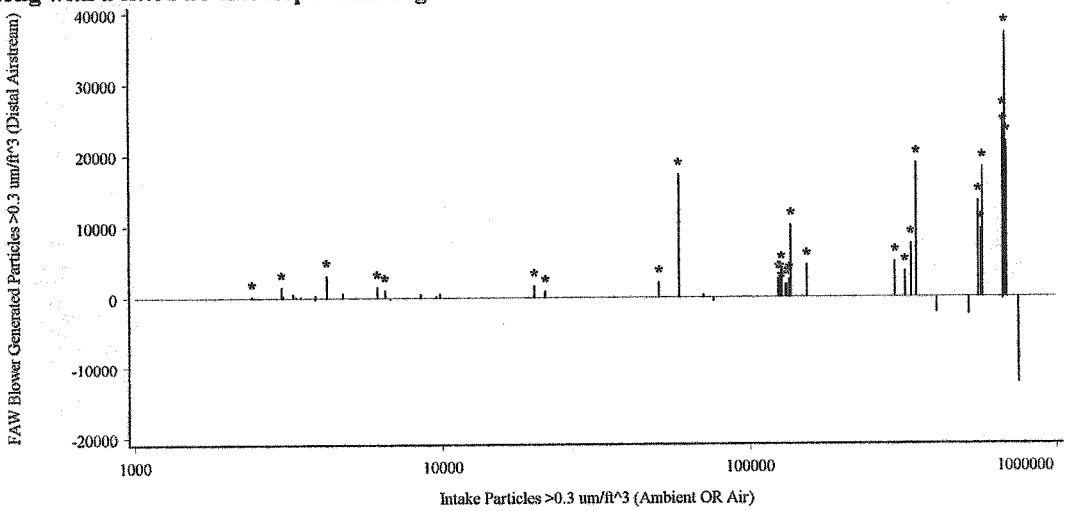

Figure 4: Forced air warming blower distal hose airflow particulate emissions above (or below) what would be expected based upon the measured efficiency of each filter and intake air particulate levels. *FAW blowers having signifigant particulate emissions in excess of expected ($P<0.05$).

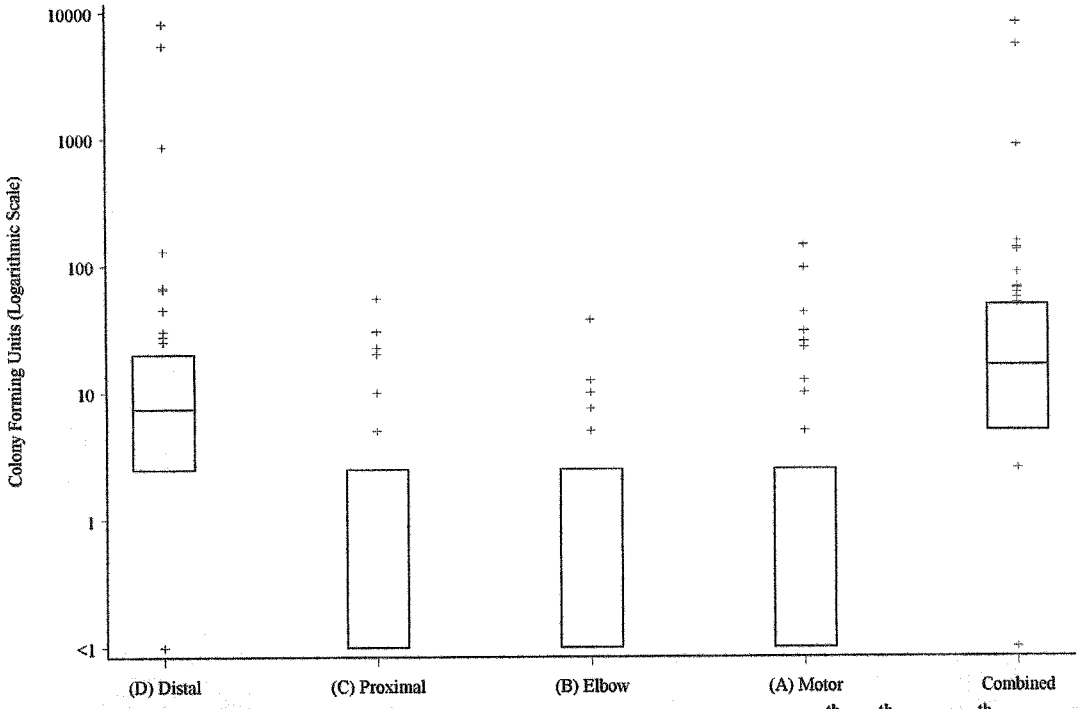

Figure 5: Detected colony forming units by sampling location, reported as 25th, 50th, and 75th quantiles with marked outliers.

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*Response to Reviewers

Ms. Ref. No.: AJIC-D-10-00049R1
Title: Forced Air Warming Blowers - An Evaluation Of Filtration Adequacy And Airborne Contamination Emissions In The Operating Room
American Journal of Infection Control

Dear David,

Thank you for this revision, which we are about ready to accept. However, we simply do not have the space to publish all of the figures and tables you have included. Please limit figures and tables to a MAXIMUM of 5 total. Thank you

Ok, we cut down the figures & tables to 5 in total. Also, we included 2 schematic diagrams we would like included in the electronic repository associated with the manuscript. These figures will be important to any engineers/scientists skilled in the art of filtration whom are looking to replicate the present study.

Also, all 2nd round changes needed to condense figures and legends are highlighted in red.

If you decide to revise your submission, please submit a list of changes or a rebuttal against each point which is being raised when you subit the revised manuscript.

To submit a revision, please go to http://ees.elsevier.com/ajic/ and login as an Author.

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Yours sincerely,

Elaine L. Larson, Ph.D., CIC
Editor
American Journal of Infection Control

For further assistance, please visit our customer support site at http://epsupport.elsevier.com. Here you can search for solutions on a range of topics, find answers to frequently asked questions and learn more about EES via interactive tutorials. You will also find our 24/7 support contact details should you need any further assistance from one of our customer support representatives.

Figure(s) for electronic repository
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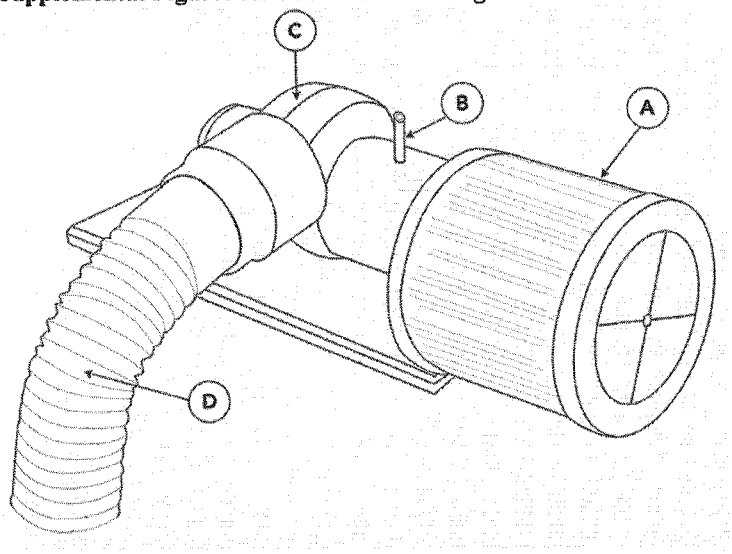
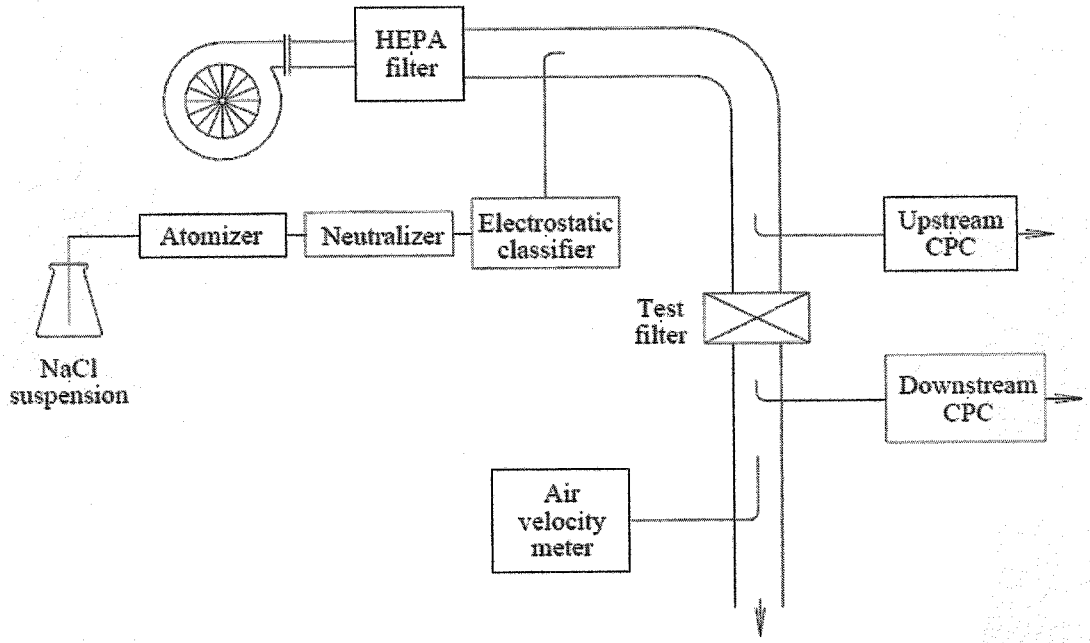
Supplemental Figures for Filtration Challenge Test Fixtures



Portable challenge test fixture for assessing intake filter performance in the operating room. Ambient operating room air is drawn through the pleated gas filter (A) and sampled through a centrally located pitot tube (B). A downstream blower (C) produces the airflow, which is vented away from the sampling area towards the floor through a flexible ducting (D).



Filtration industry standard challenge test fixture for assessing intake filter retention efficiency. The apparatus produces a monodisperse sodium chloride aerosol challenge for rating filter efficiency over a range of particle sizes.

AFFIDAVIT

STATE OF MINNESOTA)
)
COUNTY OF HENNEPIN)

Scott Douglas Augustine, being duly sworn on his oath, states as follows:

1. My name is Scott Douglas Augustine. I am a medical doctor specializing in anesthesiology.

2. In 1984 I invented the medical device that came to be known as Bair Hugger patient warming. Through my company (initially called Augustine Medical, Inc. but now called Arizant, Inc.), I introduced forced-air patient warming ("FAW") to America and the world. Through our support of clinical research, medical professionals have come to understand the importance of maintaining the patient's core body temperature during surgery.

3. In 2004 I sold my interest in Arizant. I no longer have any affiliation with the company or with the Bair Hugger product. Subsequent to selling my interest in Arizant, however, I learned of several significant problems with FAW and with the Bair Hugger system in particular. Many of the problems are detailed in the MDR filed by Dr. Robert Gauthier.

4. At the 2007 meeting of the American Association of Anesthesiologists, I communicated to several employees of Arizant the information contained in the brochure entitled "Blowing Air Is Risky!" Such information included the following:

- A department of public health in the U.S. called Bair Hugger blowers "reservoirs of infection."
- Particle counters measured more than 50 million bacteria-sized particles per hours spewing from Bair Hugger blowers.
- An outbreak of multi-drug resistant *Acinetobacter* had been traced to the inside of Bair Hugger blowers, as reported in *Infection Control and Hospital Epidemiology*.
- Germ colonies could be cultured by swabbing inside Bair Hugger units and by impacting the air blown from the hose on a culture plate.

Copies of the brochure were provided to several Arizant employees, including senior management.

5. In 2009, in order to determine the extent of contamination of Bair Hugger blowers, doctors arranged to sample the blowers used in the University Hospital in Caen, France. The day before the sampling of the blowers was to begin, however, I learned that all 80 of the blowers had been removed from service by Arizant and replaced with new blowers. The contamination testing, of course, was cancelled. Based on an approximate retail cost of $1,400, the effort to avoid disclosure of the contamination cost Arizant $112,000.

6. A similar event occurred in Engand in 2010. There, orthopedic surgeon Michael Reed was scheduled to begin sampling Bair Hugger blowers for contamination at a National Health Service hospital in Northumbria. Shortly before the sampling could begin, however, the blowers were removed from the hospital by Arizant.

7. Beginning in 2009, UK surgeon Prof. David Leaper lead a team conducting research regarding bacterial contamination of Bair Hugger blowers and the impact of waste hot air from FAW blowers on laminar flow. Dr. Leaper's research was published in *Orthopedic Reviews* and has been accepted for publication in the *American Journal of Infection Control.* In 2010, however, I began receiving reports that Dr. Leaper had been verbally abused by Arizant employees because of his research. I also learned that Dr. Leaper met with Arizant executive Robert Buehler and was asked, among other things, to conduct research for Arizant. Shortly thereafter, in June, 2010, Dr. Leaper informed me that he was withdrawing from all further research regarding the contamination of FAW blowers and laminar flow disruption.

8. At the 2009 meeting of the American Society of Anesthesiologists I communicated to several executive employees of Arizant that the waste heat from FAW destroys the protection of the laminar flow ventilation used in ultra-clean operating rooms. Several watched the video that is attached to the MDR filed by Dr. Gauthier as Annex L. Arizant Chief Scientist Al Van Duren watched the video several times, commenting only, "I didn't know that, " and "I didn't think the air would do that."

9. Because of my years as CEO of Arizant, I am aware of the company's practice of removing FAW blowers from the field after several years of use, "refurbishing" them by replacing filters and hoses, checking electronics, and

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9. Because of my years as CEO of Arizant, I am aware of the company's practice of removing FAW blowers from the field after several years of use, "refurbishing" them by replacing filters and hoses, checking electronics, and

cleaning the exterior of the blower—and then returning the blowers to the field, often to a different hospital. To my knowledge, the interior air-flow path of the blower is not cleaned during this "refurbishment" process. While I cannot be precise, I estimate that a significant percentage of the blowers in use in the United States are "refurbished."

Dated: July 1, 2010

Scott M Augustine MD
Signature

Name: Scott Augustine

Address: 9017 Cavell Cir.

City/State/Zip: Bloomington, MN 55438

Telephone: 952-465-3502

Subscribed and sworn to before me, this 1st day of July [month], 2010.

[Notary Seal]

SUSAN ELAINE SCHAEFER
Notary Public
State of Minnesota
My Commission Expires
January 31, 2015

Susan Elaine Schaef
[signature of Notary]

[typed name of Notary]

NOTARY PUBLIC My commission expires: 1/31, 2015.

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BY FAX AND POST: 0844 811 2650

Our Ref: 960337/348875

23 June 2010

Dear Sirs

Your claims in relation to Forced Air Warmers and Laminar Airflow

We act for Arizant, Inc and its subsidiaries, Arizant UK Limited and Arizant Healthcare, Inc ("**Arizant**") and are instructed as follows.

We are aware that you are the UK distributor of the Hot Dog Patient Warming Controller produced by Augustine Biomedical & Design, LLC ("**Augustine**"). We are instructed by Arizant in connection with statements made by you (detailed below) in relation to forced air warming products (the "**Offending Statements**"). Although the Offending Statements do not all expressly reference our client's Bair Hugger® product, as the market leader in forced air warmers it is clear that the Offending Statements are all directed at our client and its products. The Offending Statements are false and calculated to cause financial damage to our client and (where Bair Hugger® is expressly referenced) constitute trade mark infringement. In addition, a number of the Offending Statements are made in advertorials placed in industry journals, and these advertorials are in breach of the Committee of Advertising Practice Code ("**CAP Code**").

Emails sent to attendees of Gov Today meeting 14 October 2009

We are aware that a Gov Today meeting sponsored by Hot Dog International and entitled "Patient warming with forced-air. Is it worth the risks?" was held on 14 October 2009. Following this event, on 3 November 2009 your employee Steve Hammant-Stacey sent an email to a meeting attendee (whose name we have redacted for present purposes) (copy attached as Annex 1) in which the following Offending Statements were made:

(a) *"Further, it's now been shown that Forced Air Warming disrupts laminar air flow in an orthopaedic theatre"*;

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(b) *"Hot Dog is an air-free patient warming system that is cleaner, greener and significantly less expensive than Forced Air Warming."* [our emphasis]

Given that this email was sent to this individual attendee following attendance at the Gov Today meeting on 14 October 2009, and the email states that the recipient "may have met one of our colleagues" (our emphasis), we can only assume that this was a bulk email exercise and identical or similar emails were sent by you to all other attendees of the Gov Today meeting; meaning that the Offending Statements made therein have been published substantially more widely than an individual attendee.

www.nordicsurgical.com

We refer to your website at www.nordicsurgical.com. On this website, screen shots of which are attached (Annex 2), you make the following Offending Statements:

(a) *"Forced Air Warming Disrupts Laminar Air Flow."*

(b) *"Forced Air Warming actually disrupts the Laminar Air Flow, rendering it useless. If you work in an orthopaedic theatre, you really should see the full version of this video;"*

(c) *"Because Hot Dog is air-free, there are no risks of blowing air-borne contaminants around the operating theatre or surgical site. In contrast, particle counters have measured more than 50 million germ-sized particles per hour blowing from Forced Air Warming units".*

In addition, your website contains a video based product demonstration (the "Video") that is intended to demonstrate the effects of forced air warming on laminar airflow which features an Arizant Bair Hugger® product as an example of a forced air warmer. This too is an Offending Statement. Your website also contains a press release entitled *"Study shows forced air warming destroys protection of laminar air flow"* issued by Augustine on 23 November 2009 which contains the following Offending Statements (the "Press Release", copy attached as Annex 3):

(a) *"A new scientific study has revealed that forced air warming units in operating theatres disrupt laminar air flow systems, significantly increasing the risk of contaminating the operative site"*

(b) *"Using laser techniques to illuminate the path taken by the heated air, the research shows the laminar air flow being disrupted and dirty air being deposited into the surgical site"*

(c) *"A video of the study shows the warm air from a forced air unit being blown across the patient under the surgical drapes, dipping below the operating table (widely known by clinical staff to be a "dirty" area) and then flowing upwards as the heat rises, along with any bacteria it may be carrying, into the sterile field"*

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(d) *"Disrupting the laminar flow obviously presents a risk to patients as well as the clinical team and that is exactly what happens when forced air warming systems are turned on" (quote from Dr Scott Augustine of Augustine)*

(e) *"It is quite a disturbing study for surgeons as it shows forced air warming destroying the protection of laminar flow that hitherto they had taken for granted." (quote from Dr Scott Augustine of Augustine)*

Lastly, your website contains a brochure entitled "The Next Wave of Patient Warming" (copy attached as Annex 4) which contains the statement:

(a) "*No risk of blowing airborne contaminates around the operating theatre or surgical site*", which then refers the reader to a website www.BlowingAirIsRisky.com that contains further Offending Statements relating to contamination.

Advertorials placed in industry journals

We are aware that the following advertorials (copies of which are attached) have been published in industry journals as follows (together, the "**Advertorials**"):

- an advertorial (Annex 5) entitled *"Study shows forced air warming destroys protection of laminar air flow"* and which reproduces the text of the Press Release has been published in Inside Hospitals journal February 2010 and Operating Theatre Journal January 2010;

- an advertorial (Annex 6) entitled *"Is Forced-Air Warming Safe? Here are the facts..."* has been published in Operating Theatre Journal May 2010. This advertorial contains the following Offending Statements:

  (a) *"In recent advertisements, the leading manufacturer of forced-air warming (FAW) has offered assurances about the safety of its hot-air blowers, attempting to "set the record straight" about whether their blowers spread bacteria in operating theatres and disrupt the protection of laminar flow ventilation systems. The following compares these assertions with the facts"*

  (b) *"THE FACTS. The issue isn't air. Its heat. The physics are simple: HEAT RISES! It is well known that skin and bacteria shed from operating theatre personnel settle toward the floor. Waste heat from FAW can mobilize these contaminants and convey them to the operative site"*. The footnote to this statement cites the Video as authority for this statement.

In addition, this last advertorial made additional Offending Statements relating to the fact that the Bair Hugger system was unsafe as a result of being contaminated and thus a source of infection:

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(c) *"THE FACTS: 75 Bair Hugger® blowers were sampled in their operating room environments (6 hospitals)*

- *Micro-organisms were cultured from the internal air-flow paths of 95% of the blowers.*
- *71% of the blowers were found to be internally generating and emitting significant levels of germ-size contaminates. Some were emitting up to 300 million germ-size particles per hour, which was 40 times greater than the intake particle counts.*
- *The blowers with the highest level of particle emissions had the new Bair Hugger low efficiency (63.8%) intake filters."*

The footnote cites an unattributed and as yet unpublished paper in support.

(d) *"A recent study co-authored by Prof. David Leaper, Chair of NICE's Surgical Site Infection Guideline Development Group, was published in Orthopedic Reviews. Prof. Leaper's team sampled 25 blowers from the leading manufacturer in operating theatres. The findings:*

- *Pathogenic bacteria were cultured from the internal air-flow paths of 94% of the blowers.*
- *32% of the blowers tested were emitting internally generated airborne contamination."*

(e) *"THE FACTS: The NICE Guideline also cites studies stating as follows:*

- *One study concluded that FAW is a "potential source of nosocomial infection that may be due to colonisation in the machines distal to the filters".*
- *Although filters should protect against entrained bacteria, "microbial pathogens were detected in about 50% of the FAW devices when the air was sampled directly" from the blower.*
- *Even a small number of organisms from contaminated air "may come into contact with the surgical area and cause serious complications".*
- *"Growth of bacteria was found in swab samples... suggesting that risk assessment should be undertaken before using FAW"."*

The footnote cites of course the National Institute for Health and Clinical Excellence's "The Management of inadvertent perioperative hypothermia in adults" PP 372-374 of April 2008 (the "Nice Guidelines")

Given that contact details for you (your website) are given in the Advertorials published in Inside Hospitals journal February 2010 and Operating Theatre Journal May 2010 and these

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Advertorials mention Augustine's warming systems (by reference in the Inside Hospitals Advertorial and by name in the May 2010 Operating Theatre Journal Advertorial) of which you are the UK distributor, it is reasonable to assume that these Advertorials were placed in these journals and endorsed by you. Similarly, as the Advertorial published in Operating Theatre Journal January 2010 is in the same terms as the Advertorial published in Inside Hospitals journal February 2010, it is reasonable to assume that this Advertorial too was placed and endorsed by you. If any of the assumptions that we have made are incorrect, please let us know.

The Offending Statements

The Offending Statements fall broadly into two categories

- Those alleging an interruption of laminar flow, which for convenience we refer to as "Offending Statements (Laminar Flow)".
- Those alleging that the use of the Bair Hugger forced air warmer in operating theatres increases the risk of infections because they are a source of contamination or infection, which for convenience we refer to as "Offending Statements (Contamination)"

The Falsity of the Offending Statements (Laminar Flow)

The Offending Statements (Laminar Flow) were clearly intended to convey, and will have conveyed, to anyone reading or seeing them, including Arizant's customers, that the use of the Bair Hugger forced air warmer in operating theatres increases the risk of infections because it disrupts the laminar air flow in operating theatres to the extent that it negates the beneficial effect such a system is intended to provide, or that they otherwise increase the risk of surgical site infections. These Offending Statements (Laminar Flow) can have no other coherent meaning and this meaning is false.

The Video is shot under "simulated operating room" conditions using theatrical smoke. It is misleading to make comparisons in the Video with what occurs in real-life operating rooms. For example, you imply that theatrical smoke behaves in the same way as actual fomites (where there is no clinical analysis to support it) and you also state that the filter was removed from the FAW system (when it is obvious that the intentional alteration of a medical device will affect its proper function).

Forced air warming and Arizant's Bair Hugger® system do not disrupt the laminar air flow in operating theatres and do not increase the risk of infection. There have been many studies documenting the clinical benefits of forced air warming and maintaining normothermia but none has identified forced air warming as the source of surgical site infection, and one landmark study (*Kurz A, Sessler DI, Lenhardt R, "Perioperative normothermia to reduce the incidence of surgical-wound infection and shorten hospitalization" N. Engl. J. Med. May 9 1996;334(19):1209-1215*) carried out using a Bair Hugger® system, specifically found a reduction in the incidence of surgical site infections (SSIs) resulting from FAW use. As a result of evidence put forth by the Kurz study and other studies, forced air warming had sufficient substantiation to be recommended by NICE for the prevention and treatment of inadvertent perioperative hypothermia. Some materials to the contrary cited by Augustine either deeply misconstrue the evidence or cite papers sponsored by Augustine.

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Our client relies on the following findings from published articles and studies to demonstrate the falsity of the Offending Statements (Laminar Flow) and in support of the fact that forced air warming does not disrupt the laminar air flow in operating theatres and does not increase the risk of surgical site infections or contamination:

1. ***Sharp, R J., T. Chesworth, et al (2002) "Do warming blankets increase bacterial counts in the operating theatre field in a laminar-flow theatre?" J Bonne Joint Surg BR 84(4): 486-488.***

   This study analysed air quality within a laminar-flow theatre where forced air warming blankets were used. The results (as summarised in the Abstract of the report) *"suggest that the patient warming system does not influence bacterial counts at the operating site in an ultraclean air-ventilated theatre ...."*.

2. ***Miyazaki, H. M. Sato, et al (2007) "Forced-air warmer did not increase the risk of contamination caused by interference of clean airflow." Anesthesiology. 107: A1594.***

   This study noted that some physicians are concerned about the risk of contamination caused by turbulence of the airflow and that the study was conducted to examine whether the forced-air warmer increases the risk of contamination. The results of this study showed that *"visualised airflow around operating table and warmer blankets was not interfered with [by] the forced-air warmer. No turbulence was found in any situations of warmer and blanket (with or without surgical drape, middle of blanket or margin of blanket, above blanket or below blanket)"* and *"we could not find any interference of the down draft of OR's cleaning air system, also there is no increasing of bacteria contamination with using of warmer"*.

3. ***Moretti, B., A. M Larocca, et al (2009). "Active warming systems to maintain perioperative normothermia in hip replacement surgery: a therapeutic aid or a vector of infection?" Journal of Hospital Infection 73(1): 58-63.***

   The aim of this study, as outlined in its summary, was to assess the risk of contamination of the surgical site correlated to the use of the Bair Hugger® blanket during hip replacement surgery. It found that *"In light of the results reported here, the Bair Hugger system does not seem to pose a real risk of nosocomial infections, whilst it does offer the advantage of preventing the potentially grave consequences induced by hypothermia during major orthopaedic surgical procedures."*

In addition, our client relies on the following recently conducted study which clearly demonstrates that forced air warming causes minimal disruption to laminar air flow and does not increase the risk of surgical site infections. As you will see from the attached letter dated 19 April 2010 (Annex 7), your supplier Augustine appreciates Dr Memarzadeh's expertise. (To further outline the credentials of Dr Memarzadeh, please reference the attached credentials at Annex 8.)

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